

**HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
OCTOBER 28, 2015
APPLICATION SUMMARY**

NAME OF PROJECT: Alere Women's and Children's Health

PROJECT NUMBER: CN1506-025

ADDRESS: 1926 Hayes Street, Suite 111
Nashville, (Davidson County), Tennessee 37203

LEGAL OWNER: Alere Women's and Children's Health, LLC

1926 Hayes Street, Suite 111
Nashville, Tennessee 37203

OPERATING ENTITY: Not Applicable

CONTACT PERSON: John Wellborn
615-665-2022

DATE FILED: June 15, 2015

PROJECT COST: \$84,000

FINANCING: Cash Reserves

PURPOSE FOR FILING: Addition of 22 counties to an existing 14-county service area of a licensed home care organization approved in Matria Healthcare, Inc. Nashville, CN9807-043A, limited to high risk obstetrical patients.

DESCRIPTION:

Alere Women's and Children's Health (Alere) is requesting Certificate of Need approval to expand its service area from 14 to 34 counties through the addition of 22 counties located in parts of the Middle Tennessee Grand Division area of the state as identified in Table 6 on page 38 of the application. The agency was approved in Matria Healthcare, Inc., CN9807-043A, for the establishment of a home care organization in a 14-county service area to provide home health services to high-risk obstetrical and diabetes patients in conjunction with home uterine monitoring devices and other home medical equipment

services. Alere has operated the home health agency (HHA) in Nashville for approximately 17 years and is 1 of 3 Alere Women's Health licensed HHAs in Tennessee. Alere's parent company provides specialized home health care to high risk females and newborns nationwide with locations in approximately 20 states. Per the applicant's response to Item 4 a. and 4.m, the applicant continues to provide the in-home skilled nursing services for high risk obstetrical patients consistent with the scope of services approved in CN9807-043A.

Note to Agency Members: The applicant states throughout the application it is able to provide post-partum newborn assessments should the need arise; however since the original application (CN9807-043A) was limited to high risk obstetric patients, the same limitation applies to this application as well.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.
2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

3. Using recognized population sources, projections for four years into the future will be used.
4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

The applicant states that the specialized nature of its existing licensed home health organization's provision of in-home services to high risk females of childbearing age approved in CN9807-043A is not comparable to the need formula used to predict the need by county for entire county populations of all ages. Further, the lack of comparable utilization data from existing agencies in the proposed 22-county additional service area (approximately 72 agencies) for

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the target high-risk female population of childbearing age impacts the ability to provide an estimate of need for in-home services to this unique population.

Following Steps 1-4 above, the Department of Health report based on 2014 (Final) data indicates that residents of the proposed 22-county additional service area will need home health care in 2019; however, approximately 19,472 patients are projected to be served in 2019 by existing home health organizations resulting in a net excess or surplus of approximately (11,321).

It appears that this application does not meet the criterion.

5. Documentation from referral sources:

- a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

During initial staff review, the applicant provided support letters from physician and managed care health insurance referral sources that attest to their support for the applicant's proposed 22-county additional service area. Their names are noted in the July 31, 2015 supplemental response (Supplemental 2). Additional support letters have been provided during the 60 day reviewing agency cycle effective August 1, 2015.

It appears that this criterion has been met.

- b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The nature and scope of cases are described in the support letters from the physicians noted above. Additional information from Alere is illustrated in the table on page 30 of the application.

It appears this criterion has been met.

- c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided letters from potential patients in the July 31, 2015 supplemental response.

It appears that this criterion has been met.

- d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The applicant is an existing home care organization approved in CN9807-043A and that has been licensed by the Tennessee Department of Health since 1999. The agency has been serving high risk obstetrical patients in 14-counties of Middle Tennessee for the past 17 years. The applicant only provides in-home skilled nursing services for high-risk females. The same service will be provided to residents of the proposed 22-county additional service area under Alere's existing license.

It appears this criterion has been met.

- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
 - a. The average cost per visit by service category shall be listed.

Review of the 2014 Joint Annual Report revealed \$637,027 of total revenue from payors for services provided to 186 patients (\$3,425/patient) in its 14-county licensed service area on 1,623 visits and 2,433 hours during the 12-month reporting period. However, the applicant states that it is reimbursed on a bundled negotiated rate basis by TennCare MCOs and private payors (please see comments on pages 31-32 of the application and page 11 of Supplemental 1). As such, the applicant alleges that it cannot provide separate costs and charges on a per visit or per hour basis that could be used to compare to the average costs per visit/hour of existing home health agencies in the applicant's proposed 22-county additional service area.

It appears this criterion may not apply to the applicant.

- b. The average cost per patient based upon the projected number of visits per patient shall be listed.

As noted above, the applicant states it is reimbursed by TennCare and private managed care organizations on a negotiated, bundled per patient rate basis. For the proposed 22-county additional service area, the

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applicant projects \$277,947 in gross revenues on 41 high risk female patients in Year One (\$6,779/patient), decreasing to \$96,109 in net revenues (\$2,344/patient) after deductions for contractual adjustments, charity and bad debt. Per clarification provided on page 11 of Supplemental 1, the applicant's proposed average gross charge is \$6,779 in Year 1 compared to average gross charges of other agencies that ranged from approximately \$3,113/patient - \$9,517/patient during the 2014 JAR reporting period (group average gross charge of approximately \$5,539.40/patient

It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Summary

Alere Women's and Children's Health (Alere), an existing, unique provider of specialty home care services for high risk females of childbearing age, is seeking Certificate of Need approval to expand its licensed service area approved in CN9807-043A from 14 to 34 counties in Tennessee. The applicant proposes to provide in-home nursing services by licensed obstetrical registered nurses (RN) to high risk females of childbearing age that reside in the proposed 22-county additional service area under physician ordered plans of care. Alere's home office will coordinate operations in the 22-county additional service area through its existing office at 1926 Hayes Street in Nashville. Alere had no deficiencies during its last annual TDH licensure survey in December 2014.

The applicant is 1 of 3 licensed Alere home health agencies in Tennessee with offices in Nashville, Chattanooga and Memphis and is supported by regional clinical centers staffed by RNs and pharmacist that electronically monitor health care status of Alere's patients and participate in their care. The applicant's parent company holds Joint Commission accreditation for all of its home care organizations in 20 states across the county.

High risk obstetrical home health patients that will be served by the applicant in the 22-county additional service area are expected to be predominately TennCare managed care organization (MCO) recipients at a rate that is consistent with Alere's current 72% or higher TennCare MCO payor mix. Other forms of coverage include contracts with commercial plans, including Aetna, Cigna,

Humana and United Health Care, private and self-pay sources. Medically indigent patients will continue to be served, as necessary.

The obstetrical RN in-home skilled nursing service activities required in connection with the care of high risk OB patients are described in detail in the application, including overviews of the HHA's scope of services (pages 10 -11) and benefits (pages 15-20). The roles of key clinical staff are discussed in Supplemental 1 (pages 4 and 5). Key clinical categories include the following: preterm labor education with nursing surveillance and 17P drug administration; nausea and vomiting in pregnancy; diabetes in pregnancy; managing hypertension disorders in pregnancy; and, coagulation disorders. *Note: review of the clinical services description in the application revealed that 17P or Makena is a skilled nursing drug administration treatment prescribed under physician orders. The drug is administered by the obstetrical RN weekly from 16 weeks to approximately 37 weeks gestation to reduce incidence of recurrent preterm birth.*

Ownership

Alere Women's and Children's Health, LLC has been registered in Tennessee since August 2005.

- The applicant's parent company is Alere Health, LLC whose parent is OptumHealth Care Solutions, Inc. These entities are ultimately owned through other subsidiaries by United Health Group, a publically traded company.
- Alere Health, LLC was formed as a Delaware Corporation effective January 7, 2009. The parent company was formed as a result of a merger between Matria Healthcare and Artemis LLC.
- The applicant LLC has no individuals with membership interests.
- For more information about the ownership of the applicant LLC, please see the applicant's responses on pages 2 and 3 of Supplemental 1, and the company profile information included in United Health Group's 10K report filed with the United States Security and Exchange Commission (SEC) for the period ending December 31, 2014. The SEC report was submitted as an attachment to Supplemental 1.

Facility Information

- The parent office will not change as a result of the project to add 22 counties to the current licensed 14-county service area. The office will remain at its existing location on Hayes Street in Nashville.
- There is no construction, renovation or modification required to implement the proposed project.

Project Need

- Meet demand for in-home skilled nursing services for high risk obstetrical (OB) patients referred by their physicians as being high risk for preterm delivery.
- Specialized in-home OB nursing services provide potential to reduce preterm deliveries, expensive hospital admissions and infant mortality rates.
- Need for access to in-home skilled nursing care by low income high risk obstetrical patients regardless of their ability to pay. *Note: The applicant provided a comparison to other agencies and a detailed analysis of their potential caseloads (females of childbearing age) on pages 40 (a)-40(q) of the application.*
- Need to expand service area geographic footprints of Alere HHAs in Tennessee for greater ease of contracting with TennCare MCOs statewide for in-home nursing care of high risk obstetrical patients enrolled in TennCare.

Note to Agency members: Per the Department of Health Report project summary, based on 2014 data, 8,149 service area residents of all ages in the applicant's proposed 22-county additional service area will need home health care in 2019; however 19,472 patients are projected to be served in 2019 resulting in a net excess of (11,321). Please note that this need is calculated for all home health patients of ages and sex, not just high risk obstetrical patients needing in-home obstetrical RN services.

Service Area Demographics

- The applicant's proposed 22-county additional service area is located in major portions of the Middle Tennessee Grand Division. The total population is estimated at 517,543 residents in calendar year (CY) 2015 increasing by approximately 3.1% to 533,911 residents in CY2019.
- The overall statewide population is projected to grow by 3.7% from CY2015 to CY2019.
- The female age 15-44 population comprises approximately 18.3% of the 22-county total population compared to 19.7% statewide.
- The female age 15-44 population is expected to increase by 5.6% from 94,942 residents in CY2015 to 100,286 residents in CY2019 compared to 2.4% statewide.
- As of April 2015, approximately 22.5% of the proposed service area population was enrolled in TennCare compared to 21% statewide.

Sources: Tennessee Department of Health population projections May 2013, Division of Policy, Planning and Assessment, Office of Health Statistics; U.S. Census Bureau QuickFacts, Bureau of TennCare.

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Service Area Historical Utilization

Using licensure and provider utilization data from the provider Joint Annual Report for Home Health Agencies maintained by the Tennessee Department of Health (JAR), the applicant identified approximately 72 existing licensed home health agencies in the proposed 22-county additional service area (PSA).

- The name of the agency, location of parent office, licensed counties and utilization for patients of all ages from 2012-2014, including utilization available from the JAR for males and females in the 18-64 age cohort is provided in detail on pages 42(a)-42(q) of the application.
- As a whole, the 72 agencies served approximately 96,036 patients statewide in 2012 increasing by 5% to 100,882 patients in 2014.
- In 2014, approximately 18,364 patients or 18.2% of the 100,882 total patients served in Tennessee by the 72 agencies resided in the applicant's proposed 22-county additional service area. A summary of their utilization is shown in the table below.

Home Health Patients Served by Existing Agencies in Proposed 22-County PSA

Year	Total TN Patients All ages (M/F)	PSA Patients All ages (M/F)	PSA Patients 18-64 (M/F)*	PSA Patients 18-64 (Female only)
2014	100,882	18,364	4,733	2,367

**Note: utilization data for female patients in the 15-44 age cohort (Alere's target population) is not captured in the JAR. The applicant estimates approximately 50% of the 18-64 male/female age cohort are females.*

Applicant's Historical and Projected Utilization

The applicant served 186 patients from its existing licensed 14-county primary service area (PSA) in 2014. The historical and projected utilization of the applicant's home health agency (HHA) is shown in the table below.

Patients Served by Applicant's HHA, 2012-2017

	Patients 2012	Patients 2013	Patients 2014	% Change '12-'14	2016 Year1	2017 Year2
Existing 14-county PSA	196	202	186	-5.1%	290	331
22-county additional PSA					41	42
Combined Total	196	202	186	-5.1%	331	373
TNCare/Medicaid Patients	152	158	134	-13.4%	236	266

Source: provider JAR; CN1506-025

Note to Agency Members: In developing projected utilization, the applicant calculated a 0.043% use rate for the age 15-44 female population of its existing

14-county PSA and applied the rate to the proposed 22-county additional service area.

The table above reflects the following:

- Total patients and TennCare/Medicaid patients served by the applicant declined by 5.1% and 13.4%, respectively, from 2012-2014 (*Note: the applicant participates in other state Medicaid programs*).
- High risk obstetrical patients of the proposed 22-county additional service area are expected to account for approximately 12.4% of the applicant HHA's total patient caseloads in Year 1
- Projected utilization of the 22-county additional service area was determined by using the applicant's existing female age 15-44 population use rate as calculated in the tables on pages 44(d) and 44(e) of the application.
- On average, TennCare/Medicaid patients accounted for approximately 148 or 75.9% of 195 total average patients/year from 2012-2014. The applicant projects a 71.3% TennCare patient mix in Year 1 of the project.
- *Note: although not shown in the table above, the average length of stay or duration of treatment of Alere's high risk obstetrical patients can be determined from the provider JAR using discharges and total discharge days. Review of the applicant's 2014 JAR revealed 134 patient discharges totaling 13,842 total discharge days for an average of 97 days/patient (3.2 months) during the 12-month 2014 JAR reporting period.*

Project Cost

Major costs of the \$84,000 total estimated project cost include:

- Legal/administration/consulting fees - \$65,000 or 77.4% of total cost.
- Moveable Equipment -\$16,000 or 19% of total cost.
- The actual capital outlay is approximately \$84,000.

Historical Data Chart

The applicant provided a historical data chart on page 49 of the application showing the utilization and financial performance of its home health operations for services provided to high-risk obstetrical patients in its current 14-county licensed service area.

- Alere realized favorable net operating income of \$417,968 in 2012 decreasing to \$133,898 in 2013 and \$219,378 in 2014.
- Average annual Net Operating Income (NOI) was favorable at approximately 33.7% of annual net operating revenue for the year 2014.

Projected Data Chart

The applicant provided two projected data charts, one for the proposed 22-county additional service area and a combined chart for the applicant's proposed 34-county service area. Highlights from the 2 Projected Data Charts are shown in the table below.

Applicant's Historical and Projected Financial Performance, 2014-2016

Projected Fiscal Performance	Existing HHA 2014 *	Proposed 22-County Additional PSA-Year 1	Combined Year 1 (2016)
TN Patients	186	41	331
Gross Revenue	\$1,786,408	\$277,947	\$2,246,623
Average Gross Revenue/patient	\$8,932/patient	\$6,779/patient	\$6,787/patient
Charity (estimated patients)	\$22,985 (3 patients)	\$2,779 (1 patient)	\$22,466 (3 patients)
Net Revenue	\$650,204	\$96,109	\$776,829
Average Net Revenue/patient	\$3,251/patient	\$2,344/patient	\$2,347/patient
Operating Costs	\$430,826	\$57,591	\$505,052
Operating Costs/patient	\$2,316/patient	\$1,404/patient	\$1,526/patient
Net Operating Income (NOI)	\$219,378	\$38,518	\$271,777
NOI as a % of Gross Operating Revenue	12.3%	13.9%	12.1%

Notes: * 2014 and Year 1 include total projected revenues & expenses for patients served in TN and other states. The applicant participates in other state Medicaid programs. In 2014, 186 of 200 total patients were patients residing in Tennessee.

The table above and other highlights identified from the Projected Data Charts on pages 50 and 51 of the application are noted as follows:

Proposed 22-County Additional Service Area

- The financial performance of the project appears to be favorable as proceeds from operating revenues cover operational costs.
- Projected total gross operating revenue increases from \$277,947 on approximately 41 patients (approximately \$6,779/patient) in Year 1 to \$284,726 on 42 patients in Year 2 (approximately \$6,779/patient).
- Net operating revenue after bad debt, charity care, and contractual adjustments is \$96,109 (\$2,344/patient) in Year 1.
- Net operating income is estimated at \$38,518 or approximately 13.9% of total gross revenue in Year 1.
- Charity care amounts to approximately 1.0% of total gross revenue in Year 1.

Combined 34-County Service Area:

- Combined projected gross operating revenue is \$2,246,623 on 331 patients served in Year 1 (\$6,787/patient).
- Combined projected net operating income is \$271,777 in Year 1 (12.1% of total gross revenue) increasing by 10.6% to \$301,032 in Year 2.

Charges

- Average gross operating revenue is approximately \$6,779.00/patient in Year 1, a decrease of approximately 24.1% from \$8,932/patient in 2014. *Note: per the applicant the decrease is expected to result from a change in the mix of therapies and services provided by Alere (Item 9, Supplemental 1).*
- The average deduction is \$4,435/patient, resulting in average net operating revenue of approximately \$2,344/patient.

Medicare and TennCare/Medicaid Payor Mix

- The applicant provides in-home services only to high risk obstetrical patients of childbearing age and does not currently hold or plan to seek Medicare provider certification.
- The applicant is heavily contracted with TennCare/Medicaid averaging approximately 75.9% of total gross annual operating revenues from 2012-2014.
- Alere projects a 71.3% TennCare/Medicaid payor mix in Year 1.

Financing

The project start-up cost of \$84,000 will be funded from cash reserves in the form of a cash transfer from OptumHealth Care Solutions, Inc, to Alere Health, LLC (applicant's owner) and subsequently the applicant. The applicant and all of the parties noted are all ultimately related through common ownership by United Health Group (UHG), a publically traded company. Please note the following

- A June 17, 2015 letter from Joel Costa, Chief Financial Officer, Optum Health Care, Inc, attests to the availability of cash on hand to fund the project as documented in the Security and Exchange filings of UHG for the year ended 12/31/2014 and quarter ending 3/31/2015.
- Review of UHG's Consolidated Balance Sheet attached to the application revealed cash and cash equivalents of \$7,495,000,000 for the year ended 6/31/14, total current assets of \$23,556,000,000, and total current liabilities of \$30,623,000,000 resulting in what appears to be an unfavorable current ratio of 0.76 to 1.0. Per the response to Item 8 of the July 16, 2015 supplemental response, the applicant states there are sufficient cash

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reserves available for the minimal project cost (\$84,000) as confirmed in the 6/17/15 letter from the CFO of Optum Healthcare.

Note to Agency Members: Current Ratio is a general measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The applicant will employ additional obstetrical RNs to support the proposed 22-county additional service area. The applicant states that approximately 11 of the 22 counties can be covered by current Alere registered nurse employees. Please note the following:

- The applicant has a current nursing pool of 10 RNs or approximately 3.0 full time equivalents (FTEs).
- Alere plans to increase the HHA's nursing pool from 10 to 24 RNs by 2017. The additional 14 nurses amount to approximately 4.8 FTE.
- The proximity of existing nursing pool staff by county of residence to principle cities in the proposed 22-county additional service area is illustrated in the tables provided on pages 25 and 26 of the application.
- The resume of the corporate Medical Director, Norman Ryan, M.D. was provided in Supplemental 1.

Licensure/Accreditation

Alere Women's and Children's Health was initially licensed by the Tennessee Department of Health effective March, 1, 1999. Its current license expires February 11, 2016 and is in good standing as evidenced by its zero deficiency annual survey in December 2014. The applicant's Joint Commission accreditation expires May 2016. A copies of the last state survey and the July 17, 2013 Joint Commission letter are provided in the application.

Corporate documentation, copies of the office lease and additional miscellaneous material included in the original application are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in two years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent, pending or denied applications for other health care organizations in the service area proposing this type of service.

Outstanding Certificates of Need:

Pentec Health, Inc., CN1411-046A, has an outstanding Certificate of Need that will expire on August 1, 2017. The application was approved at the June 24, 2015 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump infusion and Ig-G replacement therapy services in all counties in Tennessee except Hancock, Perry and VanBuren Counties. The parent office will be located in leased space at 424 Church Street, Suite 2000, Nashville (Davidson County), TN. No branch offices are proposed. The applicant plans to utilize Pentec Health's existing pharmacy whose compounding branch site is located at the parent office at 4 Creek Parkway in Boothwyn, PA. The pharmacy has an active Tennessee license. The estimated project cost is **\$142,028.00**. *Project Status: This project was recently approved.*

Implanted Pump Management, CN1406-027A, has an outstanding Certificate of Need that will expire on August 1, 2017. The application was approved at the June 24, 2015 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The parent office will be located at 200 Prosperity Place #102, Knoxville (Knox County), TN 37932. There are no branch offices proposed for this project. The service area includes all 95 counties in Tennessee. The estimated project cost is **\$8,100.00**. *Project Status: This project was recently approved.*

Coram Alternative Site Services, Inc. d/b/a Coram Specialty Infusion Services, CN1406-017A, has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization to provide the following specialized home health services related to home infusion: administer home infusion products and related infusion nursing services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. The proposed service area includes the following Tennessee counties: Anderson, Blount, Bradley,

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Campbell, Carter, Claiborne, Cocke, Fentress, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Meigs, Monroe, Morgan, Pickett, Polk, Roane, Scott, Sevier, Sullivan, Unicoi, Union, and Washington Counties, from its licensed home infusion pharmacy which will be located at 10932 Murdock Drive, Suite 101A, Knoxville (Knox County), TN 37932. The estimated project cost is \$95,200.00. *Project Status Update: per the 7/24/15 Annual Progress Report, the agency has been licensed by TDH and services under the scope of the approved CON are expected to begin by September 15, 2015. A final project report is pending.*

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG
10/06/2015

LETTER OF INTENT

(n) the *Herald-Citizen*, which is a newspaper of general circulation in Putnam County;

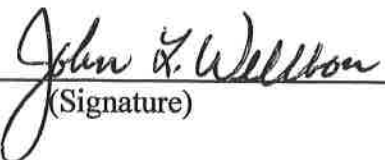
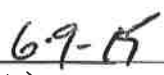
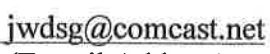
(o) the *Daily News Journal*, which is a newspaper of general circulation in Rutherford County; and

(p) the *Hartsville Vidette*, which is a newspaper of general circulation in Trousdale County.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Alere Women's and Children's Health LLC (a home health agency with its principal office in Davidson County), owned and managed by Alere Women's and Children's Health, LLC (a limited liability company), intends to file an application for a Certificate of Need to provide home health agency services exclusively limited to the care of high-risk obstetrical patients and newborns with antepartum and postpartum needs, in the following counties, to be added to its current service area, at a cost estimated at \$84,000: Cannon, Clay, Cumberland, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Moore, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren, and White.

The applicant is licensed as a Home Health Agency by the Board for Licensing Health Care facilities. The applicant's principal office is located at 1926 Hayes Street, Suite 111, Nashville, TN 37203. The project does not contain major medical equipment or initiate or discontinue any other health service; and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2015. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

(Signature) (Date) (E-mail Address)

14303469.1

COPY

Alere Women's and
Children's Health

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PART A**1. Name of Facility, Agency, or Institution**

Alere Women's and Children's Health, LLC (of Davidson County)		
<i>Name</i>		
1926 Hayes Street, Suite 111	Davidson	
<i>Street or Route</i>	<i>County</i>	
Nashville	TN	37203
<i>City</i>	<i>State</i>	<i>Zip Code</i>

2. Contact Person Available for Responses to Questions

John Wellborn	Consultant		
<i>Name</i>	<i>Title</i>		
Development Support Group	jwdsg@comcast.net		
<i>Company Name</i>	<i>E-Mail Address</i>		
4219 Hillsboro Road, Suite 210	Nashville	TN	37215
<i>Street or Route</i>	<i>City</i>	<i>State</i>	<i>Zip Code</i>
CON Consultant	615-665-2022	615-665-2042	
<i>Association With Owner</i>	<i>Phone Number</i>	<i>Fax Number</i>	

3. Owner of the Facility, Agency, or Institution

Alere Women's and Children's Health, LLC		
<i>Name</i>	<i>Phone Number</i>	
Same as in #1 above		
<i>Street or Route</i>	<i>County</i>	
Same as in #1 above		
<i>City</i>	<i>State</i>	<i>Zip Code</i>

4. Type of Ownership or Control (Check One)

A. Sole Proprietorship		F. Government (State of TN or Political Subdivision)	
B. Partnership		G. Joint Venture	
C. Limited Partnership		H. Limited Liability Company	x
D. Corporation (For-Profit)		I. Other (Specify):	
E. Corporation (Not-for-Profit)			

**PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS**

5. Name of Management/Operating Entity (If Applicable) **NA**

<i>Name</i>		
<i>Street or Route</i>		<i>County</i>
<i>City</i>	<i>State</i>	<i>Zip Code</i>

6. Legal Interest in the Site of the Institution (Check One)

A. Ownership		D. Option to Lease	
B. Option to Purchase		E. Other (Specify):	
C. Lease of: 1 yr, annually renewable	x		

7. Type of Institution (Check as appropriate—more than one may apply)

A. Hospital (Specify): General		I. Nursing Home	
B. Ambulatory Surgical Treatment Center (ASTC) Multi-Specialty		J. Outpatient Diagnostic Center	
C. ASTC, Single Specialty		K. Recuperation Center	
D. Home Health Agency	x	L. Rehabilitation Center	
E. Hospice		M. Residential Hospice	
F. Mental Health Hospital		N. Non-Residential Methadone	
G. Mental Health Residential Facility		O. Birthing Center	
H. Mental Retardation Institutional Habilitation Facility (ICF/MR)		P. Other Outpatient Facility (Specify):	
		Q. Other (Specify):	

8. Purpose of Review (Check as appropriate—more than one may apply)

A. New Institution		G. Change in Bed Complement Please underline the type of Change: Increase, Decrease, Designation, Distribution, Conversion, Relocation	
B. Replacement/Existing Facility		H. Change of Location	
C. Modification/Existing Facility		I. Other (Specify):	x
D. Initiation of Health Care Service as defined in TCA Sec 68-11-1607(4) (Specify) Home Health		Home Health Service Area Expansion, limited to high-risk OB patients, newborns, & infants	
E. Discontinuance of OB Service			
F. Acquisition of Equipment			

9. Bed Complement Data

NA

(Please indicate current and proposed distribution and certification of facility beds.)

	Current Licensed Beds	CON approved beds (not in service)	Staffed Beds	Beds Proposed (Change)	TOTAL Beds at Completion
A. Medical					
B. Surgical					
C. Long Term Care Hosp.					
D. Obstetrical					
E. ICU/CCU					
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric					
J. Child/Adolesc. Psych.					
K. Rehabilitation					
L. Nursing Facility (non-Medicaid certified)					
M. Nursing Facility Lev. 1 (Medicaid only)					
N. Nursing Facility Lev. 2 (Medicare only)					
O Nursing Facility Lev. 2 (dually certified for Medicare & Medicaid)					
P. ICF/MR					
Q. Adult Chemical Dependency					
R. Child/Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL					

10. Medicare Provider Number:	None
Certification Type:	NA
11. Medicaid Provider Number:	5440128
Certification Type:	Home Health Agency

12. & 13. See page 4

A.12. IF THIS IS A NEW FACILITY, WILL CERTIFICATION BE SOUGHT FOR MEDICARE AND/OR MEDICAID?

This is an existing home health agency. It is certified for Medicaid/TennCare; but it is not certified for Medicare because it serves exclusively high-risk pregnant women and their infants, whose age makes them ineligible for Medicare.

A.13. IDENTIFY ALL TENNCARE MANAGED CARE ORGANIZATIONS / BEHAVIORAL HEALTH ORGANIZATIONS (MCO'S/BHO'S) OPERATING IN THE PROPOSED SERVICE AREA. WILL THIS PROJECT INVOLVE THE TREATMENT OF TENNCARE PARTICIPANTS? Yes IF THE RESPONSE TO THIS ITEM IS YES, PLEASE IDENTIFY ALL MCO'S WITH WHICH THE APPLICANT HAS CONTRACTED OR PLANS TO CONTRACT.

DISCUSS ANY OUT-OF-NETWORK RELATIONSHIPS IN PLACE WITH MCO'S/BHO'S IN THE AREA.

Table One: Contractual Relationships with Service Area MCO's	
Available TennCare MCO's	Applicant's Relationship
AmeriGroup or BlueCare	contracted
United Healthcare Community Plan (formerly AmeriChoice)	contracted
TennCare Select	contracted

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment

- Alere Women's and Children's Health (Davidson County office) is a highly specialized home health agency that has served fourteen Middle Tennessee counties surrounding greater Nashville for many years. It is one of three Alere home health agencies in the State, and is part of a national network of Alere agencies supported by regional clinical centers that electronically monitor health status of Alere patients and participate in their care.
- Alere has a specialized and critically important home care mission. Alere works with, and under the direction of, patients' physicians, to provide clinically state-of-the-art home care exclusively to high-risk obstetrical patients and newborns for their antepartum and postpartum needs. Alere does not provide any other type of home care services.
- In this application, Alere is proposing to add twenty-two additional Middle Tennessee counties to the service area of its Davidson County principal office, to be able to serve referring physicians' patients wherever they may live in the Middle Tennessee region. This application is the first of three applications being submitted to expand Alere's three service areas from 34 relatively populous counties to all 95 counties, including the least populous and lowest-income counties.
- Alere is supported in its work, and in this application, by TennCare MCO's and other insurers, by perinatal centers in the region, and by numerous referring physicians who view its services and competencies as uniquely needed and beneficial.

Ownership Structure

- The applicant LLC is wholly owned by Alere Health, LLC, which is wholly owned by OptumHealth Care Solutions, Inc., which is ultimately owned by United Health Group (a publicly traded company). Attachment A.4 contains more details, an organization chart for Optum and its subsidiaries, and information on the licensed Tennessee agencies owned by the applicant.

Service Area

- The applicant's current service area consists of fourteen Middle Tennessee Counties: Bedford, Cheatham, Davidson, Dickson, Hickman, Houston, Marshall, Maury, Montgomery, Robertson, Rutherford, Sumner, Williamson, and Wilson. The applicant proposes to add to its service area twenty-two additional Middle Tennessee counties: Cannon, Clay, Cumberland, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Moore, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren, and White.

Need

- Alere programs protect the lives of physician- or payer-identified, high-risk expectant mothers, and prevent many fetal and newborn health problems that impose high medical and societal costs both during, and after, the pregnancy. Alere interventions reduce costly emergency room visits, maternal hospitalizations, and newborn admissions to Neonatal Intensive Care Units. Alere's positive impacts on restraining costs of care and on increasing high quality outcomes have resulted in strong physician and insurer support, wherever it operates. Approximately 72% of this agency's patients are TennCare mothers; so its services provide special fiscal benefits to State government.
- Tennessee's new Statewide TennCare MCO's need universal availability of Alere's services throughout the State. Physicians, insurers, and patients Statewide need access to the unique levels of care and expertise that Alere staffs provide.
- Approval of this application will result in greater accessibility to care for all high-risk pregnant women in the service area, and especially for TennCare enrollees. These patients are not adequately served today.
- Because of the highly specialized nature of Alere's services, as well as its unique patient population the impact of this project on other existing providers will be minimal. The agencies now licensed for these counties served 18,364 patients in these twenty-two counties in 2014. The 43 patients Alere would serve in Year Two are less than one-fourth of 1% of those agencies' total area caseloads. And many Alere patients will be women who would otherwise be going to local Emergency Rooms and hospitals for care, rather than being cared for at home.
- Alere believes that its services are uniquely beneficial to home health patients in this area, and that high-risk pregnant women and their newborns in the proposed service area do not have adequate access to, or choice among, home care services this comprehensive, continuous, and clinically sophisticated.
- There are 72 home health agencies licensed currently to serve one or more of this project's 22 proposed new service area counties. None of them is fully dedicated to the maternal and infant patient population, as is Alere. Many of them do not serve significant numbers of female patients under the age of 65. Alere/Davidson County's TennCare payor mix is 48%; which is matched by only 9 of the 72 area agencies, with 28 of the 72 reporting no TennCare payor mix at all. Approximately 72% of Alere's total patients are TennCare enrollees, all of them pregnant women facing problem pregnancies.

Project Cost, Funding, Financial Feasibility, and Staffing

- The cost of the project is insignificant. It requires no new offices, no construction, no major medical equipment. The cost of completing a CON review process is the largest cost. The total project cost for CON purposes will not exceed \$84,000. Funding of all project costs will be provided by the parent company, United Health Group, through a cash transfer to the applicant LLC. Current and projected financial performance of the applicant agency show a positive operating margin. The expansion of the Davidson County office of Alere will require utilization of approximately 4.8 FTE's of time, from Alere's employed staff in Year Two.

B.II. PROVIDE A DETAILED NARRATIVE OF THE PROJECT BY ADDRESSING THE FOLLOWING ITEMS AS THEY RELATE TO THE PROPOSAL.

B.II.A. DESCRIBE THE CONSTRUCTION, MODIFICATION AND/OR RENOVATION OF THE FACILITY (EXCLUSIVE OF MAJOR MEDICAL EQUIPMENT COVERED BY T.C.A. 68-11-1601 *et seq.*) INCLUDING SQUARE FOOTAGE, MAJOR OPERATIONAL AREAS, ROOM CONFIGURATION, ETC.

Not applicable. There is no physical facility modification, renovation, or construction involved in this project.

APPLICANTS WITH HOSPITAL PROJECTS (CONSTRUCTION COST IN EXCESS OF \$5 MILLION) AND OTHER FACILITY PROJECTS (CONSTRUCTION COST IN EXCESS OF \$2 MILLION) SHOULD COMPLETE THE SQUARE FOOTAGE AND COSTS PER SQUARE FOOTAGE CHART.

UTILIZING THE ATTACHED CHART, APPLICANTS WITH HOSPITAL PROJECTS SHOULD COMPLETE PARTS A-E BY IDENTIFYING, AS APPLICABLE, NURSING UNITS, ANCILLARY AREAS, AND SUPPORT AREAS AFFECTED BY THIS PROJECT. PROVIDE THE LOCATION OF THE UNIT/SERVICE WITHIN THE EXISTING FACILITY ALONG WITH CURRENT SQUARE FOOTAGE, WHERE, IF ANY, THE UNIT/SERVICE WILL RELOCATE TEMPORARILY DURING CONSTRUCTION AND RENOVATION, AND THEN THE LOCATION OF THE UNIT/SERVICE WITH PROPOSED SQUARE FOOTAGE. THE TOTAL COST PER SQUARE FOOT SHOULD PROVIDE A BREAKOUT BETWEEN NEW CONSTRUCTION AND RENOVATION COST PER SQUARE FOOT. OTHER FACILITY PROJECTS NEED ONLY COMPLETE PARTS B-E.

Not applicable. There is no construction involved in this project. The proposed services will be managed by personnel in the existing Alere office in Nashville, which will require no expansion. Field staff (OB RN's who deliver the home care) will operate from their homes in counties within, or adjoining, the service area.

PLEASE ALSO DISCUSS AND JUSTIFY THE COST PER SQUARE FOOT FOR THIS PROJECT.

Not applicable. There is no construction involved in this project.

IF THE PROJECT INVOLVES NONE OF THE ABOVE, DESCRIBE THE DEVELOPMENT OF THE PROPOSAL.

The Applicant

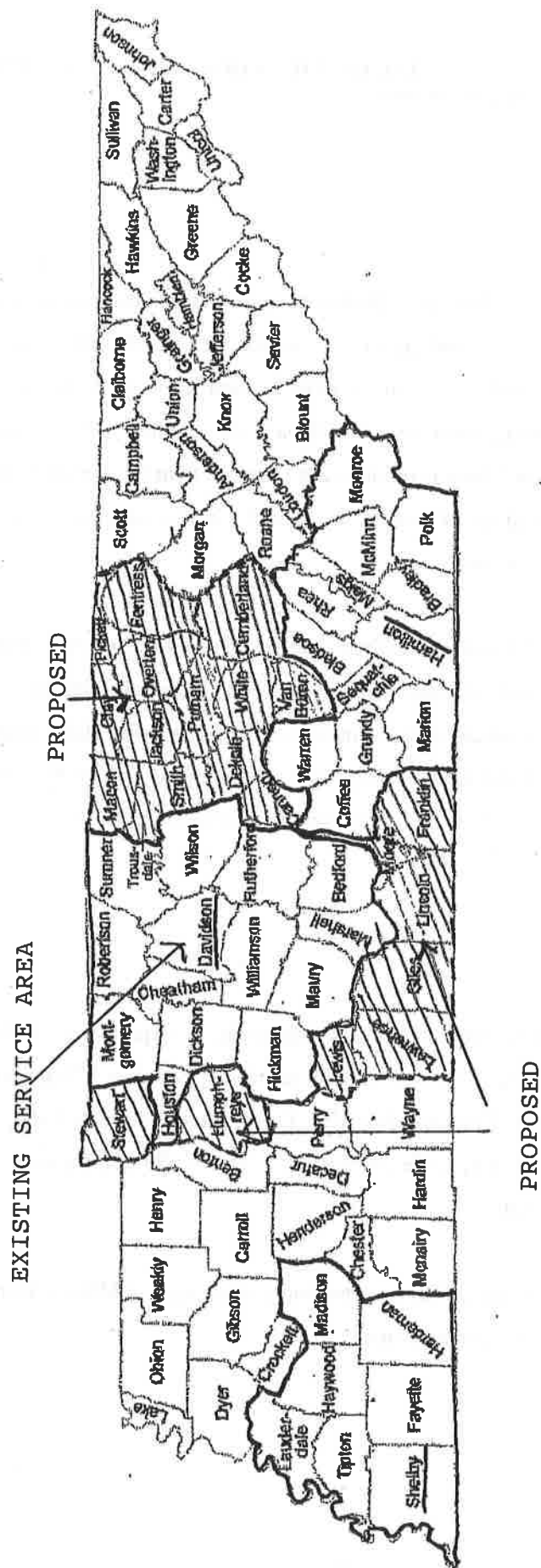
Alere Women's and Children's Health is a national leader in maternal-newborn healthcare management. Responding to physicians who need home care for their patients, Alere offers a full scope of programs from Preconception through Risk Assessment, OB Case Management, and NICU care management. In its more than 28 years of operation, Alere staff have provided care for more than three million pregnancies across America. The company is one of the world's largest employers of obstetrical RN's and obstetrical pharmacists.

Alere has served Tennessee mothers and newborns for 17 years, through three separately licensed home care agencies in Davidson, Hamilton, and Shelby Counties (as well as through an Alere medical equipment agency in Knoxville). Last year, the three home care agencies served 612 patients. Of those, 186 were served by Alere's Davidson County agency.

Service Area

Alere's Davidson County agency is proposing to expand its fourteen-county Middle Tennessee service area by twenty-two additional counties. They are Cannon, Clay, Cumberland, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Moore, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren, and White Counties.

The expansion will give Alere a 36-county coverage of Middle Tennessee. A map of the expansion follows this response.



Scope of Services

The services to be provided are those that Alere home health agencies provide currently, and have provided in authorized areas of Tennessee for decades: home care services exclusively for high-risk pregnant women and their newborns. To clarify that it will not be in significant competition with any general home health agency already authorized in the service area, Alere is requesting CON approval with that condition.

The services offered by Alere are discussed in detail in Section B.II.C (Project Need) below. They can be grouped into several major categories:

- Preterm Labor Education With Nursing Surveillance and 17P Administration Service
- Nausea and Vomiting in Pregnancy (NVP)
- Diabetes in Pregnancy
- Managing Hypertension Disorders in Pregnancy
- Coagulation Disorders

These services are provided at the physician's direction to prevent or limit numerous risks to the pregnant woman and the fetus/newborn. Risks include:

- Physical and mental impairment of the newborn;
- Intractable nausea, vomiting, and dehydration of the mother;
- Maternal/infant mortality from uncontrollable blood sugar levels (diabetes);
- Infant morbidity/mortality from uncontrolled hypertension;
- Maternal death from deep vein thrombosis and pulmonary embolism;
- First trimester spontaneous abortions;
- Recurrent preterm birth
- High costs of avoidable NICU and hospital admissions

Care Delivery Model

Physicians request Alere to deliver home care to their obstetrical patients, to provide the best possible care at home, at the lowest cost, and also to avoid when possible

the costly and time-consuming visits to the practice office, visits to the Emergency Department, and hospital admissions that often occur when high-risk pregnant patients do not have a home care resource with Alere's levels of skill and continuous committed 24/7 oversight.

To respond to physicians' requests for services to their patients, Alere utilizes its own employed pool of highly experienced, obstetrical RN's who live in communities that are quickly accessible to the patient's home.

The assigned OB RN performs a comprehensive maternal/fetal home assessment and patient education is begun. The scope of evaluations and education include patient health issues; psychosocial, environmental, and home assessments; fetal movement assessment; and training and education in self-care protocols, nutrition, social habits, and activity requirements, to name a few.

Instruction is provided in the use of supplies and equipment (e.g., insulin pumps). Barriers to care are identified and dealt with (e.g. transportation needs; childcare; ability to comply with scheduled visits). Interdisciplinary resources are identified and organized to be available appropriately, including nurses, pharmacists, and dieticians.

Appropriate daily, weekly, and continuous care management occurs through home visits by the OB RN; telephonic assessments and direction by OB RN's and OB pharmacists; telephonic reporting by the patient (as often as multiple times day and night); and 24/7 telephonic clinical and educational guidance upon request, from Alere's unique national Patient Service Centers, staffed by OB pharmacists and OB RN's.

Equipment for medication infusion is remotely monitored and controlled as needed. Supplies are provided to the home by Federal Express, UPS, and the U.S. mail, as well as during OB RN visits. Patients are diligently supervised for compliance with prescribed services, which is one of the greatest issues for many of these patients. (Pursuit of compliance is the most effective way to optimize good outcomes). Detailed patient records are maintained by the OB Nurse; digitalized records are entered at Agency offices and at the Patient Service Centers; and weekly written reports are made to the referring physician and insurer case manager as requested.

Project Costs and Funding

The project will require only a very small capital expenditure estimated not to exceed \$84,000. No additional office space need be acquired to implement the project; it will be managed from Alere/Davidson's principal office in Nashville.

The cost of the project will be funded entirely in cash, by the applicant's parent company, United Health Group (UHG). The cost will be very small, no more than \$84,000.

Staffing

Approximately 4.8 additional FTE's of time will be required to serve the 43 new patients per year that Alere expects to serve in these additional counties (based on current Alere Davidson County use rates). Those FTE's are calculated as the cumulative per diem assignments made by the 14 additional OB RNs that Alere will employ in the service area.

Home care services will be provided by obstetrical nurses employed to work as needed in counties within, or near, the proposed new service area. Alere's plan for ensuring rapid access to patients in the new counties is discussed in more detail in Section B.III.B.1 below.

B.II.B. IDENTIFY THE NUMBER AND TYPE OF BEDS INCREASED, DECREASED, CONVERTED, RELOCATED, DESIGNATED, AND/OR REDISTRIBUTED BY THIS APPLICATION. DESCRIBE THE REASONS FOR CHANGE IN BED ALLOCATIONS AND DESCRIBE THE IMPACT THE BED CHANGE WILL HAVE ON EXISTING SERVICES.

Not applicable. This project is for the expansion of an existing home health agency's service area. No facilities are included in the project.

B.II.C. AS THE APPLICANT, DESCRIBE YOUR NEED TO PROVIDE THE FOLLOWING HEALTH CARE SERVICES (IF APPLICABLE TO THIS APPLICATION):

- 1. ADULT PSYCHIATRIC SERVICES**
- 2. ALCOHOL AND DRUG TREATMENT ADOLESCENTS >28 DAYS**
- 3. BIRTHING CENTER**
- 4. BURN UNITS**
- 5. CARDIAC CATHETERIZATION SERVICES**
- 6. CHILD AND ADOLESCENT PSYCHIATRIC SERVICES**
- 7. EXTRACORPOREAL LITHOTRIPSY**
- 8. HOME HEALTH SERVICES.....**

1. Purpose of this Application

This CON application is being filed to give Alere programs broader availability to TennCare MCO's and private insurance companies that increasingly request Alere services.

TennCare MCO's will be a prime beneficiary. They are now Statewide organizations with a significant population of low-income women of childbearing age, in both urban and rural counties. Many of these women face pregnancy risks of the type addressed by Alere home care programs. The MCO's are responsible for paying their costs of healthcare. The MCO's and their patients' physicians value high-quality home care partners that can provide all needed interventional services to those women.

With appropriate home care, pregnant at-risk women can be spared significant health problems and their insurers can avoid significant costs.

But without appropriate home care, these young women will either (a) not receive needed care, resulting in increased maternal/fetal morbidity and mortality, or (b) they will have to obtain it from more costly and difficult-to-reach sources such as hospital Emergency Departments, hospital acute care units, neonatal intensive care units, and their physicians' practice offices. Obtaining specialized care at home is a much more cost-effective option, as well as being the option that has better outcomes for maternal/fetal health.

2. The Need for Alere in the Proposed Service Area

The applicant has identified seventy-two licensed home care agencies that are authorized to operate in one or more of the counties in the service area. However, Alere's entry into this service area is needed for the following reasons, among others:

- Because of its historical, long-standing focus on only problem pregnancies--and because it uses appropriate technology to supervise and provide guidance in the patient's home between personal home visits--Alere's programs provide a scope and effectiveness of care that are not routinely available from existing area agencies. Service area patients should have Alere as one of their home care options because of this expertise alone.
- Alere is one of the most TennCare-accessible agencies in Middle Tennessee, unlike many home health agencies licensed in these 22 counties. Of the 72 licensed agencies, only 9 had a TennCare payor mix as high as Alere/Davidson's TennCare payor mix. Approximately 72% of Alere/Davidson's Tennessee patients are TennCare patients.
- Many physicians and insurers who serve high-risk young pregnant women in the proposed service area want access to Alere's programs of care, because they perceive that Alere provides care programs not available elsewhere. Many home health agencies avoid serving the high-risk population due to risks of litigation and liability should the births not go well. This creates an accessibility problem for some women, regardless of their insurance source and income status.

a. Expertise and the Beneficial Impact of Alere's Care Programs

The following pages summarize the characteristics and benefits of the five major Alere programs that are proposed for these twenty-two rural counties.

Alere contends that for high-risk pregnant women and their neonates, this array of staffing, technology, 24/7 care availability, and diligence in attaining patient compliance and good outcomes, is superior on a routine basis to that of any other home health agency in the service area. It is therefore important to introduce it as a care option in these counties--especially for the TennCare population where these needs are so great.

BENEFITS OF ALERE OBSTETRICAL HOMECARE SERVICES

Program: Preterm Labor Education With Nursing Surveillance and 17P Administration Service	
Health Condition(s) Addressed:	
<ul style="list-style-type: none"> Physician has diagnosed a <u>maternal risk of preterm labor</u> (at less than 37 weeks gestation). Physician has diagnosed patient with history of previous preterm birth. Administration of 17p from 16wks to 36 & 6/7 wks gestation is prescribed to reduce incidence of recurrent preterm birth. 	
Health Risks of Condition:	
<ul style="list-style-type: none"> Premature births are associated with increased physical and mental limitations of the infant, some of which are correctible, and others of which are lifetime afflictions. 	
Costs of Conditions, Unaddressed:	
<ul style="list-style-type: none"> More emergency room visits and higher cost to the health plan Longer hospital stays and higher costs for the health plan prior to giving birth NICU (neonatal intensive care unit) and acute care stays and costs for newborns Lifetime patient and societal costs of coping with enduring limitations. 	
Alere Interventions:	
<ul style="list-style-type: none"> Comprehensive maternal/fetal home assessment and education by OB RN Comprehensive scope of evaluations and education--patient health / psychosocial, environmental, home assessments / assessments of fetal movement / training in self-care protocols, nutrition, social habits, etc. (see detailed list following this section). Weekly injections of "17P" or "Makena" by OB RN to reduce recurrent preterm births 24/7 telephonic OB nurse availability 	
Benefits of Alere Interventions:	
<ul style="list-style-type: none"> Diligent supervision by Alere OB RN's yields 97% Alere patient compliance with weekly injection requirements. Compliance is directly associated with reductions in preterm deliveries. Elimination of barriers to care (ie. Transportation, childcare issues, missing scheduled visits etc) to improve compliance with weekly injection schedule. 17P reduces preterm birth incidence by 34%. Reduced costs of ED visits, maternal hospitalizations, NICU care, and future health and societal costs. A 2006 National Institute of Medicine study of 5,609 Medicaid patients with a history of preterm delivery, who received weekly 17P injections, identified almost a 50% reduction of preterm deliveries, with a Medicaid net savings of \$8,090 per birth. 	

Note: "17P" is abbreviated name of 17 alphahydroxyprogesterone caproate.

Program: Nausea and Vomiting in Pregnancy (NVP)	
Health Condition(s) Addressed:	<ul style="list-style-type: none"> • Intractable nausea, vomiting, and dehydration (hyperemesis gravidarum) in pregnancy
Health Risks of Condition:	<ul style="list-style-type: none"> • Severe discomfort and inability to perform activities of daily living • Dehydration • Malnutrition mother/fetus
Costs of Conditions, Unaddressed:	<ul style="list-style-type: none"> • ER visits, 24hr observation stays, hospital admissions of the expectant mother to alleviate symptoms and reduce potential maternal/fetal complications.
Alere Interventions:	<ul style="list-style-type: none"> • Multi-interventional approach including dietitians, perinatal nurse clinicians, high risk obstetrical pharmacist consultation, psychosocial assessment, in home nursing support, and delivery of antiemetic-medication through a subcutaneous micro-infusion pump • Daily telephonic assessments by high risk obstetrical nurse • Dietary consultation to address maternal nutritional needs • Limited IV hydration to stabilize fluid balance and alleviate overall symptoms
Benefits of Alere Interventions:	<ul style="list-style-type: none"> • 78% increase in weight gain of mother or stabilization • 89% reduction in nausea and vomiting • Hospital admissions for such patients: 65.4% reduced to 3.3% • Reduced costs of ED visits, physician office visits, maternal hospitalizations, NICU care, future health and societal costs.

Program: Diabetes in Pregnancy
Health Condition(s) Addressed: <ul style="list-style-type: none"> • Gestational diabetes (pre-existing or pregnancy-related maternal diabetes)
Health Risks of Condition: <ul style="list-style-type: none"> • Maternal complications from out-of-control blood sugar levels • Birth complications as a result of Macrosomia (large baby) including increased risk of shoulder dystocia/injury during birth. • Elevated blood sugar levels of baby post delivery • Maternal/infant morbidity and mortality associated with uncontrolled blood sugar management
Costs of Conditions, Unaddressed: <ul style="list-style-type: none"> • 3X more likely to require pre- and post-natal hospitalizations of mother and/or newborn than in non-diabetic population; hospitalization cost of \$4,000-\$4,300 in 2010 prices (5 years ago) • Hospital admissions of this type increased 72%-75% in last decade studied
Alere Interventions: <ul style="list-style-type: none"> • Intensive programs for both insulin-requiring and non-insulin-requiring mothers, to ensure compliance with the care plan approved by patient's physician • Initial in-home education/counseling regarding nature of diabetes in pregnancy, glucose monitoring, meal planning and physical activity. • Ongoing telephonic management of patients to address blood sugar trends. • Medication management with daily assessment of blood glucose and ketones through telephonic reporting • All needed insulin and supplies are delivered to home • 24/7 OB RN & Certified Diabetic Educators (CDE) access via telephone • When using insulin pump management, ongoing monitoring of patient data and remote adjustments of medication
Benefits of Alere Interventions: <ul style="list-style-type: none"> • Alere can save an average of \$13,000 per pregnancy in total costs of care for mother and neonate • NICU admissions alone can be reduced up to 25% • 2010 Study of pre-gestational diabetes patients (insulin-dependent) showed: <ul style="list-style-type: none"> --increase in patient compliance from 8.4% on Day 1 to 69.3% on Day 4 --27% reduction in out-of-target blood glucose levels --60% improvement in compliance with blood glucose testing protocols --47% reduction in number of Type 2 diabetes patients with A1C indicator > 6% • 2010 Outcomes Study of Alere Diabetes Program vs. conventional management in the physician's office showed the following improvements in birth complications in diabetic mothers:

- Reduction in macrosomia (large birth weight) from 13.6% to 9.6%
- Reduction in hyperbilirubinemia (increased bilirubin levels) from 17.5% to 9.2%
- Reduction in hypoglycemia from 20% to 5.6%
- Reduction respiratory complications from 6.2% to 4.2%
- Reduction in shoulder dystocia from 1.4% to 0.1% (can lead to permanent nerve damage and long term disability)
- Reduction in NICU admissions from 25% to 8%

Notes, edited and paraphrased from sources indicated:

Fetal Macrosomia: In a newborn, the risks associated with fetal macrosomia increase greatly when birth weight is more than 9 pounds 15 ounces. Fetal macrosomia can complicate vaginal delivery, putting the baby at risk of injury during birth, and at increased risk of health problems after birth. [Mayo Clinic]

Hyperbilirubinemia: Excessive bilirubin in the blood, which can produce jaundice, a yellow tint to a newborn's skin and the white part of the eyes. In newborns, in rare cases, if bilirubin levels stay high and are not treated, this condition can cause brain damage resulting in serious lifelong problems. [Tabor's Cyclopedic Medical Dictionary & WebMD]

Hypoglycemia: A deficiency of blood sugar--the most common metabolic problem in newborns. The most common symptoms are jitteriness, cyanosis (blue coloring), apnea (stopping breathing), hypothermia (low body temperature), poor body tone, poor feeding, lethargy, and seizures. Major long-term consequences can include neurologic damage resulting in mental retardation, recurrent seizure activity, developmental delay, and personality disorders. Some evidence suggests that severe hypoglycemia may impair cardiovascular function. [Tabor's & Stanford Children's Health]

Dystocia: Difficult labor. It may result from either the size of the fetus or the small size of the pelvic outlet. Shoulder dystocia occurs when a baby's head is delivered but his shoulders get stuck inside the mother's body. This creates risks for both mother and baby. The underlying condition, if not treatable in advance of delivery, can make delivery by cesarean section necessary. [March of Dimes]

Program: Managing Hypertension Disorders in Pregnancy
Health Condition(s) Addressed: <ul style="list-style-type: none"> • Hypertension • Preeclampsia (formerly called “toxemia”) leading to eclampsia, a serious condition that could result in maternal and fetal morbidity and mortality
Health Risks of Condition: <ul style="list-style-type: none"> • Hypertension late in pregnancy can require the need for induced premature delivery of infant, potentially leading to increased neonatal cost and infant morbidity/mortality • High (25%) risk of preeclampsia with hypertension. Mothers with preeclampsia may experience rapid weight gain, abdominal pain, headaches, changes in reflexes, dizziness, vomiting, nausea, and vision changes. Uncontrolled PIH can lead to development of eclampsia/seizures.
Costs of Conditions, Unaddressed: <ul style="list-style-type: none"> • Longer hospital stays for mother both pre and post-partum, resulting in higher total costs of care • NICU stays for infants due to prematurity and other complications as a result of mother’s condition • Damage to organs of mother and fetus (preeclampsia)
Alere Interventions: <ul style="list-style-type: none"> • Initial in-home assessment and education pertaining to Pregnancy Induced Hypertension (PIH), education on use of equipment for daily blood pressure monitoring. • Intensive surveillance and support for patients at high risk of, or with, mild preeclampsia in the outpatient setting. • Identifies changes in condition that may indicate progression of hypertension with the need to re-admit to the hospital. • Daily weight, measurement of protein in urine, patient assessment/education • Twice daily fetal kick count • 24/7 OB nurse availability for telemetric monitoring of blood pressures and patient assessments as needed.
Benefits of Alere Interventions: <ul style="list-style-type: none"> • 2006 Study found that Alere reduced costs associated with hypertensive disorders--shortening hospital stays by 1.2 days and reducing patient costs from \$10,327 to \$4,888.

Program: Coagulation Disorders
Health Condition(s) Addressed: <ul style="list-style-type: none"> • Deep vein thrombosis (DVT), Factor V Leiden, Antiphospholipid Antibodies, Pulmonary Embolus, Prothrombin Mutations, Von Willebrand Disease
Health Risks of Condition: <ul style="list-style-type: none"> • Can cause first trimester spontaneous abortions • Untreated clotting disorders can result in deep vein thrombosis and pulmonary embolism that could result in maternal death.
Costs of Conditions, Unaddressed: <ul style="list-style-type: none"> • NA
Alere Interventions: <ul style="list-style-type: none"> • Obstetrical Pharmacist in Regional Clinical Center manages and monitors dosing of heparin to specific patient parameters • OB RN provides and reinforces patient education regarding coagulation disorders and their various complications • Provides 24/7 opportunity for patient to triage with OB RN
Benefits of Alere Interventions: <ul style="list-style-type: none"> • Reduces risks of maternal morbidity & mortality

**Table Six: Demographic Characteristics of Project Service Area
Alere Davidson County--Proposed Additional Counties
2015-2019**

Primary Service Area		Demographic Characteristics												
County	Median Age 2010 Census	Female 15-44 Population 2015	Female 15-44 Population 2019	Female 15-44 Population % Change 2015 - 2019	Total Population 2015	Total Population 2019	Female 15-44 Population % of Total Population 2015	Female 15-44 Population % of Total Population 2019	Median Household Income	TennCare Enrollees April 2015	Percent of 2015 Population Enrolled in TennCare	Persons Below Poverty Level 2015	Persons Below Poverty Level as % of Population US Census	
Cannon	41.4	2,550	2,690	5.5%	14,218	14,631	17.9%	18.4%	\$40,689	2,930	20.6%	2,531	17.8%	
Clay	45.1	1,231	1,271	3.2%	7,681	7,684	16.0%	16.5%	\$29,727	2,198	28.6%	1,582	20.6%	
Cumberland	48.3	9,344	10,578	13.2%	58,340	61,077	16.0%	17.3%	\$37,188	12,071	20.7%	10,268	17.6%	
DeKalb	41.0	3,307	3,296	-0.3%	18,996	19,172	17.4%	17.2%	\$37,482	5,159	27.2%	3,609	19.0%	
Fentress	42.3	3,268	3,445	5.4%	18,553	19,133	17.6%	18.0%	\$29,192	5,940	32.0%	4,768	25.7%	
Franklin	41.3	8,056	8,782	9.0%	41,391	42,408	19.5%	20.7%	\$42,904	7,553	18.2%	6,250	15.1%	
Giles	42.1	5,172	5,092	-1.5%	29,293	29,282	17.7%	17.4%	\$38,495	6,067	20.7%	5,712	19.5%	
Humphreys	41.9	3,221	3,239	0.6%	18,519	18,581	17.4%	17.4%	\$42,846	4,083	22.0%	2,963	16.0%	
Jackson	44.7	1,901	1,897	-0.2%	11,383	11,520	16.7%	16.5%	\$33,386	2,769	24.3%	2,777	24.4%	
Lawrence	39.7	7,473	7,592	1.6%	42,373	42,373	17.6%	17.9%	\$37,368	10,090	23.8%	8,432	19.9%	
Lewis	41.2	2,158	2,072	-4.0%	12,112	12,259	17.8%	16.9%	\$17,751	2,908	24.0%	5,727	20.1%	
Lincoln	41.8	7,221	7,872	9.0%	34,624	36,059	20.9%	21.8%	\$41,571	7,288	21.0%	5,727	16.5%	
Macon	38.7	4,444	4,685	5.4%	23,419	24,366	19.0%	19.2%	\$35,306	6,657	28.4%	5,012	21.4%	
Moore	43.3	1,153	1,219	5.7%	6,364	6,415	18.1%	19.0%	\$46,170	824	12.9%	859	13.5%	
Overton	41.6	4,030	4,195	4.1%	22,593	23,104	17.8%	18.2%	\$34,604	5,070	22.4%	4,722	20.9%	
Pickett	47.2	732	744	1.6%	4,998	4,930	14.6%	15.1%	\$35,184	1,159	23.2%	975	19.5%	
Putnam	35.9	16,236	17,436	7.4%	78,416	83,992	20.7%	20.8%	\$33,709	16,418	20.9%	19,290	24.6%	
Smith	39.9	3,717	3,893	4.7%	19,771	20,468	18.8%	19.0%	\$42,383	4,081	20.6%	3,420	17.3%	
Stewart	42.8	2,351	2,397	2.0%	13,659	14,027	17.2%	17.1%	\$39,781	2,904	21.3%	2,445	17.9%	
Trousdale	39.5	1,595	1,697	6.4%	8,275	8,667	19.3%	19.6%	\$43,034	1,926	23.3%	1,498	18.1%	
Van Buren	44.5	876	909	3.8%	5,433	5,488	16.1%	16.6%	\$33,547	1,316	24.2%	1,092	20.1%	
White	42.0	4,906	5,285	7.7%	27,132	28,275	18.1%	18.7%	\$34,474	6,877	25.3%	4,965	18.3%	
Tennessee PSA	42.1	94,942	100,286	5.6%	517,543	533,911	18.3%	18.8%	\$36,672	116,288	22.5%	101,333	19.6%	
State of Tennessee	38.0	1,306,684	1,337,422	2.4%	6,649,438	6,894,997	19.7%	19.4%	\$44,298	1,399,004	21.0%	1,170,301	17.6%	

Sources: TDH Population Projections, May 2013; U.S. Census QuickFacts; TennCare Bureau.
PSA data is unweighted average, or total, of county data.

b. Accessibility

Tennessee does not compile clinically detailed data on home health agency patients. But what is reported publicly in the Joint Annual Reports suggests that for high-risk pregnant women, there may be accessibility issues--especially for TennCare enrollees. Alere feels that one reason for this is that many home care companies are reluctant to serve them for fear of lawsuits and liabilities when pregnancies result in harm to the mother and/or the baby. Such a fear is not irrational, if the agency is not deeply experienced with this type of care.

Section C(I)5 (Utilization) later in the application contains detailed tables on the utilization of agencies in this area. In that section, Table Nine-B ranks area agencies by their percent of gross charges to TennCare patients; and Table Ten-C ranks them by the percentage of their services to women of childbearing age.

The TennCare table suggests that there is a broad lack of TennCare access to most authorized agencies in the area. Approximately 22.5% of the area's population is enrolled in TennCare. However, almost two-thirds of area home care agencies (61%) have only a TennCare payor mix of 0-10%. This cannot be fully explained by reference to the large proportion of Medicare patients served relative to younger adults. In fact, of all 72 area agencies, only 9 match or exceed Alere/Nashville's TennCare payor mix of 48% (who constitute 72% of Alere patients). These facts suggest that the market needs, and can accommodate, an exceptionally TennCare-accessible provider like Alere, that addresses a very small section of the total population and does not compete for most of its patients with most other home care providers.

The second issue raised by the data is whether pregnant women in or out of TennCare in this service area have sufficient access to these agencies when high-risk situations develop. The JAR's do not provide data on home care patients ages 15-44; but they do provide data on patients ages 18-64--a range that covered all of Alere/Davidson's pregnant patients in 2014. Although a gender breakdown of patients 18-64 years of age is not provided in the JAR's, it is reasonable to apply a 50% assumption to generally estimate the number of female patients served in that age cohort. Using that assumption, Table Ten-C in Section C(I)5 shows that in 2014, the women in this age bracket in these

22 counties who received home care for any condition totaled only 12.9% of the 18,364 patients served in these 22 counties. Agencies' service levels to these women varied between 0% and 50%--which itself implies how much variation of access there is among agencies. The table shows that 59 (or 82%) of the 72 licensed agencies had 20% or less of their area patients in this gender age group. Alere feels that a major reason for this low female service percentage at so many agencies is that they do not offer the specialized services required to serve women whose pregnancies present serious health challenges.

Another important implication of the low percentage of pre-Medicare adult women in the area's home health caseloads is that Alere's entry into these counties will not adversely impact the financial viability of existing providers. In 2014, these 72 agencies served 18,364 area patients. An estimated 2,367 were probably adult women 18-64 years of age (see Base Table 1 in the Attachments).

Alere/Davidson projects serving only 43 service area women per year in this area. Alere believes that many of these patients would not otherwise be receiving home care from any existing agency. But even in the very unlikely event that all 43 would be taken from existing agency caseloads (very unlikely), that impact would equate to less than one-fourth of one percent of these agencies' total area patients in 2014. This could not reasonably be viewed as a significant impact from an areawide planning perspective.

c. Support from Referral Sources

When Alere/Davidson was granted CON approval in 1998 to expand from a home medical equipment provider to a home health agency for high-risk pregnant women, numerous medical practices wrote strong letter of support for Alere, citing its high quality, high dependability, and the need for its services. Alere is currently requesting letters of support from physicians and insurers who have patients in the proposed service area with home care needs. These are not available at the time of filing this application. They will be provided to the Agency under separate cover.

B.II.D. DESCRIBE THE NEED TO CHANGE LOCATION OR REPLACE AN EXISTING FACILITY.

Not applicable.

B.II.E. DESCRIBE THE ACQUISITION OF ANY ITEM OF MAJOR MEDICAL EQUIPMENT (AS DEFINED BY THE AGENCY RULES AND THE STATUTE) WHICH EXCEEDS A COST OF \$2.0 MILLION; AND/OR IS A MAGNETIC RESONANCE IMAGING SCANNER (MRI), POSITRON EMISSION TOMOGRAPHY (PET) SCANNER, EXTRACORPOREAL LITHOTRIPTER AND/OR LINEAR ACCELERATOR BY RESPONDING TO THE FOLLOWING:

1. For fixed site major medical equipment (not replacing existing equipment):
 - a. Describe the new equipment, including:
 1. Total Cost (As defined by Agency Rule);
 2. Expected Useful Life;
 3. List of clinical applications to be provided; and
 4. Documentation of FDA approval.
 - b. Provide current and proposed schedule of operations.
2. For mobile major medical equipment:
 - a. List all sites that will be served;
 - b. Provide current and/or proposed schedule of operations;
 - c. Provide the lease or contract cost;
 - d. Provide the fair market value of the equipment; and
 - e. List the owner for the equipment.
3. Indicate applicant's legal interest in equipment (e.g., purchase, lease, etc.)
In the case of equipment purchase, include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Not applicable. The project contains no major medical equipment.

B.III.A. ATTACH A COPY OF THE PLOT PLAN OF THE SITE ON AN 8-1/2" X 11" SHEET OF WHITE PAPER WHICH MUST INCLUDE:

1. SIZE OF SITE (IN ACRES);
2. LOCATION OF STRUCTURE ON THE SITE;
3. LOCATION OF THE PROPOSED CONSTRUCTION; AND
4. NAMES OF STREETS, ROADS OR HIGHWAYS THAT CROSS OR BORDER THE SITE.

PLEASE NOTE THAT THE DRAWINGS DO NOT NEED TO BE DRAWN TO SCALE. PLOT PLANS ARE REQUIRED FOR ALL PROJECTS.

A site plan is not applicable. This application requests additional counties for the service area of an existing home health agency.

B.III.B.1. DESCRIBE THE RELATIONSHIP OF THE SITE TO PUBLIC TRANSPORTATION ROUTES, IF ANY, AND TO ANY HIGHWAY OR MAJOR ROAD DEVELOPMENTS IN THE AREA. DESCRIBE THE ACCESSIBILITY OF THE PROPOSED SITE TO PATIENTS/CLIENTS.

For home care, the site of service is the patient's home. The sites for this project will be in twenty-two Middle Tennessee counties. Alere/Davidson will assure accessibility to care by employing OB RN's who reside in or near these new counties. It happens that half of these proposed counties can be covered by Alere OB Nurses who are already employed by Alere. The tables on the next two pages show how Alere field staff will be able to rapidly respond to patients in the proposed counties.

(Note: Alere's staffing chart in a later section of this application projects only a few additional nursing FTE's to care for a small annual patient population. The staffing chart projects the total cumulative FTE's that will be used, not the total FTE's under contract for use as needed. The OB RN pool will have backup OB RN availability for the times when the OB RN closest to a patient's residence becomes temporarily unavailable.)

Table Two: Alere Field Staff Accessibility to Proposed Service Area		
Proposed Service Area In Which Field Staff May be Recruited		Alternative Accessible Counties Where Field Staff Already Exist* or May be Recruited
County	Principal City	Counties
Cannon	Woodbury	Rutherford*, Warren
Clay	Celina	Overton, Jackson
Cumberland	Crossville	Morgan, Overton
DeKalb	Smithville	Putnam
Fentress	Jamestown	Morgan, Overton, Scott
Franklin	Winchester	Coffee*, Marion
Giles	Pulaski	Maury*, Giles
Humphreys	Waverly	Hickman, Maury*
Jackson	Gainesboro	Putnam, Overton, Franklin
Lawrence	Lawrenceburg	Maury*
Lewis	Hohenwald	Maury*, Hickman, Dickson
Lincoln	Fayetteville	Giles, Bedford, Franklin
Macon	Lafayette	Sumner*
Moore	Lynchburg	Coffee*, Bedford, Lincoln
Overton	Livingston	Putnam, Cumberland, Fentress
Pickett	Byrdstown	Overton, Fentress
Putnam	Cookeville	Overton, Cumberland, DeKalb
Smith	Carthage	Wilson*, Macon
Stewart	Dover	Montgomery*, Wilson, Sumner
Trousdale	Hartsville	Wilson*, Sumner
Van Buren	Spencer	Warren, Cumberland
White	Sparta	Cumberland, Putnam
Cannon	Woodbury	Rutherford*, Warren

Source: Alere/Davidson management.

Note: Alere/Davidson may recruit field staff residing in the proposed service area counties (first column in table) and/or field staff residing in accessible nearby counties (second column).

The accessibility in drive time between proposed staff locations and the principal city in the county of service is shown in the following table.

Table Three: Mileage and Drive Times Between Alere Field Staff and Major Communities in the 22-County Primary Service Area			
Principal Cities in Proposed New Service Area Counties	Alternative Accessible Cities and Counties Where Field Staff Already Exist or May be Recruited	Distance in Miles	Drive Time in Minutes
Woodbury (Cannon)	Murfreesboro (Rutherford)	19.2	24
Celina (Clay)	Livingston (Overton)	17.7	24
Crossville (Cumberland)	Wartburg (Morgan)	34.8	49
Smithville (DeKalb)	Cookeville (Putnam)	28.0	36
Jamestown (Fentress)	Wartburg (Morgan)	35.7	57
Winchester (Franklin)	Manchester (Coffee)	24.9	33
Pulaski (Giles)	Columbia (Maury)	30.5	39
Waverly (Humphreys)	Centerville (Hickman)	39.4	44
Gainesboro (Jackson)	Cookeville (Putnam)	18.8	27
Lawrenceburg (Lawrence)	Columbia (Maury)	37.8	44
Hohenwald (Lewis)	Columbia (Maury)	32.9	43
Fayetteville (Lincoln)	Pulaski (Giles)	29.2	34
Lafayette (Macon)	Gallatin (Sumner)	30.2	39
Lynchburg (Moore)	Manchester (Coffee)	25.0	34
Livingston (Overton)	Cookeville (Putnam)	21.2	27
Byrdstown (Pickett)	Livingston (Overton)	20.0	27
Cookeville (Putnam)	Livingston (Overton)	21.2	27
Carthage (Smith)	Lebanon (Wilson)	21.0	28
Dover (Stewart)	Clarksville (Montgomery)	30.8	36
Hartsville (Trousdale)	Lebanon (Wilson)	16.1	23
Spencer (Van Buren)	McMinnville (Warren)	21.1	30
Sparta (White)	Crossville (Cumberland)	27.2	34

Source: Google Maps, June 2015

Note: Alere/Davidson may recruit field staff within the proposed service area counties (first column in table) or as an alternative within accessible nearby counties (second column, which contains highest priority alternative location).

B.IV. ATTACH A FLOOR PLAN DRAWING FOR THE FACILITY WHICH INCLUDES PATIENT CARE ROOMS (NOTING PRIVATE OR SEMI-PRIVATE), ANCILLARY AREAS, EQUIPMENT AREAS, ETC.

See attachment B.IV.

IV. FOR A HOME CARE ORGANIZATION, IDENTIFY

- 1. EXISTING SERVICE AREA (BY COUNTY);**
- 2. PROPOSED SERVICE AREA (BY COUNTY);**
- 3. A PARENT OR PRIMARY SERVICE PROVIDER;**
- 4. EXISTING BRANCHES AND/OR SUB-UNITS; AND**
- 5. PROPOSED BRANCHES AND/OR SUBUNITS.**

Not applicable. The application is not for a home care organization.

C(I) NEED

C(I).1. DESCRIBE THE RELATIONSHIP OF THIS PROPOSAL TO THE IMPLEMENTATION OF THE STATE HEALTH PLAN AND TENNESSEE'S HEALTH: GUIDELINES FOR GROWTH.

A. PLEASE PROVIDE A RESPONSE TO EACH CRITERION AND STANDARD IN CON CATEGORIES THAT ARE APPLICABLE TO THE PROPOSED PROJECT. DO NOT PROVIDE RESPONSES TO GENERAL CRITERIA AND STANDARDS (PAGES 6-9) HERE.

B. APPLICATIONS THAT INCLUDE A CHANGE OF SITE FOR A HEALTH CARE INSTITUTION, PROVIDE A RESPONSE TO GENERAL CRITERION AND STANDARDS (4)(a-c).

Guidelines for Growth 2000: Project-Specific Guidelines
Home Health Services

1. The need for home health agencies/services shall be determined on a county by county basis.
2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services that county. The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.
3. Using recognized population sources, projections for four years into the future will be used.
4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

This projection is now done by the Tennessee Department of Health (TDH). The most current version is a 2014-2019 projection of need, by county. The TDH projections for the proposed service area are attached on the following page. None of these 22 counties is projected to have an unmet need for additional home healthcare services.

However, that projection is not relevant to this project. The projection methodology is for all types of home health needs and it uses a 1.5% planning factor for an entire county population. By contrast, this Alere project deals with only the female population of childbearing age, and within that group only the high-risk pregnancies.

Joint Annual Report of Home Health Agencies - 2014 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2019 vs. 2014)**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2014 Pop.	Use Rate	Projected 2019 Pop.	Projected Capacity	Projected Need (.015 x 2019 Pop.)	Need or (Surplus) for 2019
Tennessee	1,482	1,496	174,329	6,658,532	0.0261812964	7,035,572	184,200	105,534	(78,667)
Cannon	16	17	543	14,258	0.0380838827	14,740	561	221	(340)
Clay	6	6	296	7,874	0.0375920752	7,879	296	118	(178)
Cumberland	14	15	1,754	59,990	0.0292382064	64,687	1,891	970	(921)
DeKalb	20	18	673	19,344	0.0347911497	20,074	698	301	(397)
Fentress	7	7	998	18,548	0.0538063403	19,192	1,033	288	(745)
Franklin	14	13	1,510	41,763	0.0361564064	42,543	1,538	638	(900)
Giles	12	10	1,019	29,680	0.0343328841	29,802	1,023	447	(576)
Humphreys	15	12	715	18,851	0.0379290223	19,136	726	287	(439)
Jackson	11	11	428	11,965	0.0357709987	12,320	441	185	(256)
Lawrence	14	11	1,753	42,761	0.0409952995	43,689	1,791	655	(1,136)
Lewis	11	8	423	12,565	0.0336649423	13,002	438	195	(243)
Lincoln	13	13	1,224	34,275	0.0357111597	35,286	1,260	529	(731)
Macon	14	16	940	23,059	0.0407649941	24,023	979	360	(619)
Moore	11	11	85	6,659	0.0127646794	6,994	89	105	16
Overton	10	10	845	23,025	0.0366992400	24,090	884	361	(523)
Pickett	7	6	261	5,169	0.0504933256	5,251	265	79	(186)
Putnam	17	15	2,625	77,237	0.0339863019	83,063	2,823	1,246	(1,577)
Smith	17	17	626	19,884	0.0314825991	20,685	651	310	(341)
Stewart	11	11	367	13,798	0.0265980577	14,313	381	215	(166)
Trousdale	14	15	350	8,233	0.0425118426	8,651	368	130	(238)
Van Buren	11	11	230	5,622	0.0409107079	5,684	233	85	(147)
White	13	12	1,052	26,979	0.0389932911	28,278	1,103	424	(678)
	278	265	18,717	521,539		543,382	19,472	8,149	(11,321)

Source: TDH; counties not in service area deleted by CON applicant and totals inserted.

*Most recent year of Joint Annual Report data for Home Health Agencies

**Data is projected four years from the year the Home Health data was finalized, not the actual year of Home Health data.

Population Data Source: The University of Tennessee Center for Business and Economic Research (UTCBER) Projection Data Files, reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.

Note: Population data will not match the UTCBER data exactly due to rounding.

The State Health Plan and the Guidelines for Growth appropriately focus on home health needs in general, for an entire population; but this project should not be reviewed only under an irrelevant criterion. Other criteria in the Guidelines recognize the need to give weight to local physician expressions of need and to types of care that are not otherwise available to the entire service area.

5. Documentation from referral sources:

a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

After submittal of this application, the applicant will seek to provide letters of referral support from physicians and nurses who make home health referrals, as well as from insurer organizations.

b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

Table Four below provides Alere's estimate of its Year One case composition from a clinical perspective.

Table Four: Estimated Year One Composition of Cases By Clinical Need Alere Women's and Children's Health / Davidson County	
Type of Patient	Number (%)
Preterm Education, Nursing Surveillance, & 17P Administration	30
Nausea and Vomiting in Pregnancy	5
Diabetes in Pregnancy	4
Hypertension Disorders in Pregnancy	2
Coagulation Disorders in Pregnancy	1
Total Projected Patients, Year One	42 (100%)

Source: Alere management.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

These are being gathered by the applicant for submission under separate cover.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

This information is discussed above in Section B.II.C. The applicant is a national leader in the provision of comprehensive and specialized care to high-risk pregnant women and their fetuses/newborns. The expertise, continuity, and effectiveness of Alere's maternal/infant care programs are not equaled by any other provider. There is no other provider now in the service area with such a focused or experienced care program for this very vulnerable patient population. Few of the currently authorized providers are as accessible to high-risk pregnant patients--particularly TennCare patients--as is Alere.

- 6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.**
- a. The average cost per visit by service category shall be listed.**
 - b. The average cost per patient based upon the projected number of visits per patients shall be listed.**

Table Five-A below provides information on the average costs and charges by hours and visits, as reported by a random sampling of home care agencies who now operate in this service area. However, they do not allow a meaningful comparison to Alere's cost and charge structure. Alere negotiates with all its insurers, including Medicaid MCO's, a comprehensive "bundled" rate that covers all Alere services. Those negotiated rates vary; they are proprietary and confidential. Alere does not have separate costs, or charges, that are identifiable for "hours" or "visits". The Alere information in Table Five-B below is Alere/Davidson's calculated average gross charge per patient, derived from the Projected Data Chart of the applicant. Alere's only field staff are OB RN's and their services are skilled nursing under the JAR format.

Table Five-A: Cost & Charge Data of Agencies Currently in the Service Area Skilled Nursing				
Agency*	Cost/Visit	Charge/Visit	Cost/Hour	Charge/Hour
1	\$108	\$108	No JAR Data Is Reported For This	NR
2	\$136	\$136		\$40
3	\$106	\$106		\$44
4	\$NR	\$175		\$55
5	\$97	NR		NR
Alere/Dav'son	NR	NR		NR

Source: 2014 Joint Annual Reports; and Alere management.

*Key to Agencies:

1. Elk Valley Home Health Care Agency, LLC (76032)
2. Home health Care of Middle Tennessee, LLC (19584)
3. Quality Home Health (25044)
4. Vanderbilt Community and Home Services (19394)
5. NHC Homecare (75024)

Table Five-B: Alere/Davidson's Average Charges Per Patient (All Counties)		
	Year One--2015	Year Two--2016
Patients	42	43
Total Gross Revenue Per Patient	\$6,787	\$6,786

Source: Maxim management.

The Framework for Tennessee's Comprehensive State Health Plan

Five Principles for Achieving Better Health

The following Five Principles for Achieving Better Health serve as the basic framework for the State Health Plan. After each principle, the applicant states how this CON application supports the principle, if applicable.

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.

Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

The purpose of this project is to provide specialized health services to high-risk pregnant women and their newborns, under the medical direction of patient physicians. The coordinated efforts of Alere's specialized OB RN's with the patients' physicians will reduce the suffering and costs of maternal and fetal/newborn health problems in the project service area.

2. Access to Care

Every citizen should have reasonable access to health care.

Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

The project will increase the access of service area women, including TennCare enrollees, to cost-effective specialized services that enhance the health of mothers and babies and reduce the costs of their care during high-risk pregnancies.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system. The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.

The project is intended to provide broader accessibility to Alere's cost-effective and health-enhancing programs of maternal/fetal home care. The project will provide leadership in setting standards of care for pregnant women in the service area. It will improve efficiency of care by reducing the need for distressed pregnant women to seek

care in expensive emergency rooms or hospital beds, when that can be avoided by skillful home care incorporating 24/7 telephonic support and constant monitoring by skilled clinicians.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

The applicant is licensed in Tennessee and is fully Joint-Commission accredited. Alere has earned the Joint Commission's Gold Seal ranking for the excellence of its programs.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

The project is a home care service, not a facility; as such it is not involved in the rotational training of health professionals.

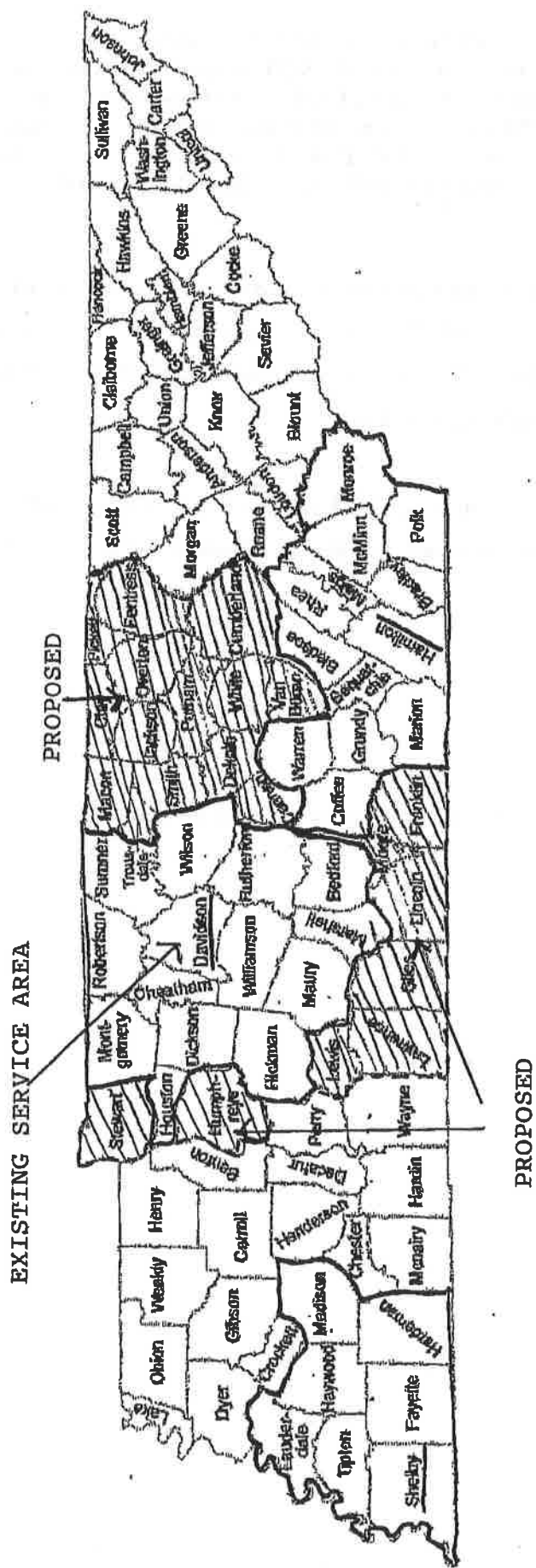
C(I).2. DESCRIBE THE RELATIONSHIP OF THIS PROJECT TO THE APPLICANT'S LONG-RANGE DEVELOPMENT PLANS, IF ANY.

If this application is approved, Alere may wish to expand into additional counties including the least populous and lowest-income counties.

C(D).3. IDENTIFY THE PROPOSED SERVICE AREA AND JUSTIFY THE REASONABLENESS OF THAT PROPOSED AREA. SUBMIT A COUNTY-LEVEL MAP INCLUDING THE STATE OF TENNESSEE CLEARLY MARKED TO REFLECT THE SERVICE AREA. PLEASE SUBMIT THE MAP ON A 8-1/2" X 11" SHEET OF WHITE PAPER MARKED ONLY WITH INK DETECTABLE BY A STANDARD PHOTOCOPIER (I.E., NO HIGHLIGHTERS, PENCILS, ETC.).

The proposed service area consists of 22 Middle Tennessee counties. They are Cannon, Clay, Cumberland, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Moore, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren, and White Counties.

A service area map showing the location of the service within the State of Tennessee is provided after this page, and also in Attachment C, Need--3 at the back of the application.



C(I).4.A DESCRIBE THE DEMOGRAPHICS OF THE POPULATION TO BE SERVED BY THIS PROPOSAL.

Please see Table Six following this page.

The service area population is more aged than the State, having a median age of 42.1 years compared to the State's 38.0 years.

The service area's population of women of childbearing age (15-44) is 18.3% of its total population. Between this year and 2019, that is projected to increase by 5.6%, more than twice the 2.4% Statewide rate of increase for this gender age group.

The service area counties' average household income is 17% lower than the Tennessee State average: \$36,672 compared to \$44,288. Consistent with this, their TennCare enrollments are higher: 22.5% for the service area, compared to 21% for the State. Also consistent is the fact that the area has a higher percentage (19.6%) of its residents living below the Federal "poverty level" than does the State as a whole (17.6%).

C(I).4.B. DESCRIBE THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION, INCLUDING HEALTH DISPARITIES, THE ACCESSIBILITY TO CONSUMERS, PARTICULARLY THE ELDERLY, WOMEN, RACIAL AND ETHNIC MINORITIES, AND LOW-INCOME GROUPS. DOCUMENT HOW THE BUSINESS PLANS OF THE FACILITY WILL TAKE INTO CONSIDERATION THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION.

Pregnancy risks have a higher incidence rate among low-income women than among all women of that age group. So financial accessibility to care becomes an important issue for women whose pregnancies put them and their babies at risk. The applicant, Alere/Davidson County, is extraordinarily accessible to low-income TennCare mothers. In 2014, 72% of its Tennessee patients were TennCare enrollees. The Alere agency's 48% TennCare payor mix (2014 JAR) was much higher than the TennCare payor mix of 63 of the 72 home care agencies operating in this service area--44 of whom had less than a 10% TennCare payor mix, 28 of that number having zero TennCare. More than 22% of the area population is enrolled in TennCare currently.

Alere will also remedy a common problem among home care agencies, which is a reluctance to serve many (or any) high-risk pregnant patients regardless of patient insurance--due to limited expertise in this highly specialized field and due to the heightened legal liability that can be involved with treating such patients. Due to its exclusive focus on this one type of patient, its years of experience with their special needs, and its excellent history of success in delivering effective care that reduces bad outcomes for mothers and babies at risk, Alere is uniquely positioned to handle these cases. It will vigorously pursue service to this underserved segment of the population, to the benefit not only of patients but also to those who pay the costs of care for their pregnancies and their newborns.

C(I).5. DESCRIBE THE EXISTING OR CERTIFIED SERVICES, INCLUDING APPROVED BUT UNIMPLEMENTED CON'S, OF SIMILAR INSTITUTIONS IN THE SERVICE AREA. INCLUDE UTILIZATION AND/OR OCCUPANCY TRENDS FOR EACH OF THE MOST RECENT THREE YEARS OF DATA AVAILABLE FOR THIS TYPE OF PROJECT. BE CERTAIN TO LIST EACH INSTITUTION AND ITS UTILIZATION AND/OR OCCUPANCY INDIVIDUALLY. INPATIENT BED PROJECTS MUST INCLUDE THE FOLLOWING DATA: ADMISSIONS OR DISCHARGES, PATIENT DAYS, AND OCCUPANCY. OTHER PROJECTS SHOULD USE THE MOST APPROPRIATE MEASURES, E.G., CASES, PROCEDURES, VISITS, ADMISSIONS, ETC.

A series of tables following this page (and in the Attachments) identify existing area providers of home care and relevant aspects of their utilization. Those tables are:

CURRENTLY AUTHORIZED AGENCIES

Table Seven-A: Alphabetically, the names of the agencies currently licensed for any of the service area counties.

Table Seven-B: By State ID number, the agencies currently licensed for any of the service area counties.

(Tables Seven-C and -D listed next are reference tables 14 pages in length. For brevity of this section, they have been placed in the "Miscellaneous" Attachments at the back of the application.)

Table Seven-C: By county, alphabetically the names of the agencies currently licensed for each of the service area counties. *(See Attachment--Miscellaneous)*

Table Seven-D: By county, by State ID number the names of the agencies currently licensed for each of the service area counties. *(See Attachment--Miscellaneous)*

UTILIZATION OF CURRENTLY AUTHORIZED AGENCIES

Table Eight: By agency name alphabetically,

- Patients served in all its authorized counties, 2012-2014
- Patients served in the 22-county Alere project area, 2014
- Estimated female patients 18-64 who were served in 2014
- TennCare gross revenues as % of total gross revenues (i.e. payor mix)

Table Nine-A: Agency TennCare Payor Mix (By Agency Name)

- Table Nine-B: Agency TennCare Payor Mix (Ranked by Percentage)
- Table Ten-A: Agency Dependence on All Area Patients and
on Female Age 18-64 Area Patients (By Agency Name)
- Table Ten-B: Agency Dependence on All Area Patients and
on Female Age 18-64 Area Patients (Ranked by Dependence on
All Area Patients)
- Table Ten-C: Agency Dependence on All Area Patients and
on Female Age 18-64 Area Patients (Ranked by Dependence on
Area's Female Patients 18-64)
- Base Table 1: In Attachments. This long table provides the county-specific patient
data whose area totals are used in the other Tables.

**Table Seven-A: HHA's Licensed to Serve in Additional Area Requested by
Alere Davidson County (Alphabetical)**

Health Statistics ID	Agency County	Agency
26054	Franklin	Amedisys Home Care
33103	Hamilton	Amedisys Home Health
67024	Overton	Amedisys Home Health
75054	Rutherford	Amedisys Home Health
19674	Davidson	Amedisys Home Health (Cumberland Bend)
19024	Davidson	Amedisys Home Health (Glen Echo Rd)
47202	Knox	Amedisys Home Health Care
75064	Rutherford	Amedisys Home Health Care
19684	Davidson	Amedisys Home Health Services
95084	Wilson	American National Home Health
19714	Davidson	Angel Private Duty and Home Health, Inc.
09065	Carroll	Baptist Memorial Home Care & Hospice
19504	Davidson	Brookdale Home Health Nashville
47062	Knox	Camellia Home Health of East Tennessee
19724	Davidson	Careall
89074	Warren	Careall Home Care Services
60074	Maury	Careall Homecare Services
92025	Weakley	Careall Homecare Services
26024	Franklin	Caresouth HHA Holdings of Winchester, LLC
33383	Hamilton	Continucare Healthservices, Inc II
19734	Davidson	Coram CVS Specialty Infusion Services
47402	Knox	Covenant Homecare
14024	Clay	Cumberland River Homecare
36025	Hardin	Deaconess Homecare
52024	Lincoln	Deaconess Homecare
76032	Scott	Deaconess Homecare
95034	Wilson	Deaconess Homecare I
19494	Davidson	Elk Valley Health Services Inc
19614	Davidson	Friendship Home Health Agency
89084	Warren	Friendship Home Health, Inc.
63034	Montgomery	Gateway Home Health Clarksville
16024	Coffee	Gentiva Health Services
19084	Davidson	Gentiva Health Services
33093	Hamilton	Gentiva Health Services
95074	Wilson	Gentiva Health Services
47182	Knox	Gentiva Health Services 2 (Girling Health Care)
94074	Williamson	Guardian Home Care of Nashville, LLC
40075	Henry	Henry County Medical Center Home Health
02024	Bedford	Heritage Home Health
71014	Putnam	Highland Rim Home Health Agency
80064	Smith	Highpoint Homecare
83114	Sumner	Highpoint Homecare
19544	Davidson	Home Care Solutions, Inc

**Table Seven-A: HHA's Licensed to Serve in Additional Area Requested by
Alere Davidson County (Alphabetical)**

Health Statistics ID	Agency County	Agency
06063	Bradley	Home Health Care of East Tennessee, Inc
19584	Davidson	Home Health Care of Middle Tennessee
19364	Davidson	Intrepid USA Healthcare Services
71084	Putnam	Intrepid USA Healthcare Services
89064	Warren	Intrepid USA Healthcare Services
52044	Lincoln	Lincoln Medical Home Health & Hospice
60044	Maury	Maury Regional Home Services
33253	Hamilton	Memorial Hospital Home Health
33033	Hamilton	NHC Homecare
60024	Maury	NHC Homecare
74054	Robertson	NHC Homecare
75024	Rutherford	NHC Homecare
60084	Maury	Quality First Home Care
25044	Fentress	Quality Home Health
25034	Fentress	Quality Private Duty Care
39035	Henderson	Regional Home Care - Lexington
41034	Hickman	St. Thomas Home Health
16034	Coffee	Suncrest Home Health
19324	Davidson	Suncrest Home Health
21024	DeKalb	Suncrest Home Health
63044	Montgomery	Suncrest Home Health of Nashville, Inc.
03025	Benton	Tennessee Quality Homecare - Northwest
20045	Decatur	Tennessee Quality Homecare - Southwest
32122	Hamblen	Univ. of TN Med. Ctr Home Health/Hospice Service
19394	Davidson	Vanderbilt Community & Home Services
94084	Williamson	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs
27085	Gibson	Volunteer Home Care, Inc
20055	Decatur	Volunteer Homecare of West Tennessee
19694	Davidson	Willowbrook Home Health Care Agency

Source: Department of Health Licensure - 9/12/2014 (Updated by HSDA Registry 4/7/2015)

**Table Seven-B: HHA's Licensed to Serve in Additional Area Requested by
Alere Davidson County (By State ID Number)**

Health Statistics ID	Agency County	Agency
02024	Bedford	Heritage Home Health
03025	Benton	Tennessee Quality Homecare - Northwest
06063	Bradley	Home Health Care of East Tennessee, Inc
09065	Carroll	Baptist Memorial Home Care & Hospice
14024	Clay	Cumberland River Homecare
16024	Coffee	Gentiva Health Services
16034	Coffee	Suncrest Home Health
19024	Davidson	Amedisys Home Health (Glen Echo Rd)
19084	Davidson	Gentiva Health Services
19324	Davidson	Suncrest Home Health
19364	Davidson	Intrepid USA Healthcare Services
19394	Davidson	Vanderbilt Community & Home Services
19494	Davidson	Elk Valley Health Services Inc
19504	Davidson	Brookdale Home Health Nashville
19544	Davidson	Home Care Solutions, Inc
19584	Davidson	Home Health Care of Middle Tennessee
19614	Davidson	Friendship Home Health Agency
19674	Davidson	Amedisys Home Health (Cumberland Bend)
19684	Davidson	Amedisys Home Health Services
19694	Davidson	Willowbrook Home Health Care Agency
19714	Davidson	Angel Private Duty and Home Health, Inc.
19724	Davidson	Careall
19734	Davidson	Coram CVS Specialty Infusion Services
20045	Decatur	Tennessee Quality Homecare - Southwest
20055	Decatur	Volunteer Homecare of West Tennessee
21024	DeKalb	Suncrest Home Health
25034	Fentress	Quality Private Duty Care
25044	Fentress	Quality Home Health
26024	Franklin	Caresouth HHA Holdings of Winchester, LLC
26054	Franklin	Amedisys Home Care
27085	Gibson	Volunteer Home Care, Inc
32122	Hamblen	Univ. of TN Med. Ctr Home Health/Hospice Service
33033	Hamilton	NHC Homecare
33093	Hamilton	Gentiva Health Services
33103	Hamilton	Amedisys Home Health
33253	Hamilton	Memorial Hospital Home Health
33383	Hamilton	Continuicare Healthservices, Inc II
36025	Hardin	Deaconess Homecare
39035	Henderson	Regional Home Care - Lexington
40075	Henry	Henry County Medical Center Home Health
41034	Hickman	St. Thomas Home Health

**Table Seven-B: HHA's Licensed to Serve in Additional Area Requested by
Alere Davidson County (By State ID Number)**

Health Statistics ID	Agency County	Agency
47062	Knox	Camellia Home Health of East Tennessee
47182	Knox	Gentiva Health Services 2 (Girling Health Care)
47202	Knox	Amedisys Home Health Care
47402	Knox	Covenant Homecare
52024	Lincoln	Deaconess Homecare
52044	Lincoln	Lincoln Medical Home Health & Hospice
60024	Maury	NHC Homecare
60044	Maury	Maury Regional Home Services
60074	Maury	Careall Homecare Services
60084	Maury	Quality First Home Care
63034	Montgomery	Gateway Home Health Clarksville
63044	Montgomery	Suncrest Home Health of Nashville, Inc.
67024	Overton	Amedisys Home Health
71014	Putnam	Highland Rim Home Health Agency
71084	Putnam	Intrepid USA Healthcare Services
74054	Robertson	NHC Homecare
75024	Rutherford	NHC Homecare
75054	Rutherford	Amedisys Home Health
75064	Rutherford	Amedisys Home Health Care
76032	Scott	Deaconess Homecare
80064	Smith	Highpoint Homecare
83114	Sumner	Highpoint Homecare
89064	Warren	Intrepid USA Healthcare Services
89074	Warren	Careall Home Care Services
89084	Warren	Friendship Home Health, Inc.
92025	Weakley	Careall Homecare Services
94074	Williamson	Guardian Home Care of Nashville, LLC
94084	Williamson	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs
95034	Wilson	Deaconess Homecare I
95074	Wilson	Gentiva Health Services
95084	Wilson	American National Home Health

Source: Department of Health Licensure - 9/12/2014 (Updated by HSDA Registry 4/7/2015)

Table Eight: Patients Served By Home Health Agencies Licensed in Alere Davidson's Proposed Counties

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2012 JAR Total Patients Served in TN	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2014 Total Patients Served in Alere's Proposed 22-County Service Area
26054	Franklin	Amedisys Home Care	82	9/19/83	1,074	1,150	1,002	590
33103	Hamilton	Amedisys Home Health	113	7/1/81	3,343	2,878	2,564	17
67024	Overton	Amedisys Home Health	191	1/17/84	1,277	1,453	949	878
75054	Rutherford	Amedisys Home Health	207	6/7/84	554	661	535	14
19674	Davidson	Amedisys Home Health (Cumberland Bend)	254	7/1/88	2,943	5,182	2,148	207
19024	Davidson	Amedisys Home Health (Glen Echo Rd)	38	2/2/76	1,598	2,008	1,508	40
47202	Knox	Amedisys Home Health Care	150	8/2/84	5,420	5,354	4,391	1
75064	Rutherford	Amedisys Home Health Care	5	8/23/84	1,431	1,582	1,372	388
19684	Davidson	Amedisys Home Health Services	68	10/1/17	388	23	210	0
95084	Wilson	American National Home Health (Friendship)	600	10/24/00	358	311	305	77
19714	Davidson	Angel Private Duty and Home Health, Inc. (Friendship)	622	3/24/09	73	123	79	10
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	213	262	283	6
19504	Davidson	Brookdale Home Health Nashville (Innovative Senior)	289	1/13/83	504	677	587	0
47062	Knox	Camellia Home Health of East Tennessee	144	9/7/78	1,556	1,716	1,732	127
19724	Davidson	Careall	295	7/5/84		1,562	1,665	937
89074	Warren	Careall Home Care Services	265	1/31/84	337	637	974	290
60074	Maury	Careall HomeCare Services	194	2/9/84	224	609	881	415
92025	Weakley	Careall HomeCare Services	276	6/16/83	2,668	2,036	2,337	87
26024	Franklin	Caresouth HHA Holdings of Winchester, LLC	83	1/29/76	1,371	2,030	2,444	522
33383	Hamilton	Continuicare Healthservices, Inc II	108	5/7/76	17	8	7	0
19734	Davidson	Coram CVS Specialty Infusion Services	624	1/30/13		11	26	2
47402	Knox	Covenant HomeCare	133	7/14/78	3,946	3,953	4,792	0
14024	Clay	Cumberland River HomeCare	135	12/28/82	236	392	393	393
95034	Wilson	Deaconess HomeCare (Cedar Creek HH Care)	282	12/18/78	1,210	1,222	1,706	597
52024	Lincoln	Deaconess HomeCare (Elk Valley)	161	2/25/76	704	842	1,294	778
76032	Scott	Deaconess HomeCare (Elk Valley)	211	9/20/85	352	394	603	35
36025	Hardin	Deaconess HomeCare (Gericare, LLC)	290	2/11/83	1,244	1,330	2,122	183
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	245	277	293	51
19614	Davidson	Friendship Home Health Agency	323	3/4/96	1,093	845	745	4
89084	Warren	Friendship Home Health, Inc.	619	2/12/08	1,345	1,724	1,721	610
63034	Montgomery	Gateway Home Health Clarksville	186	6/20/84	1,067	949	1,340	80
16024	Coffee	Gentiva Health Services	30	8/1/80	629	424	320	76
19084	Davidson	Gentiva Health Services	49	8/22/84	1,239	1,003	831	0
33093	Hamilton	Gentiva Health Services	100	8/24/84	268	328	348	0
95074	Wilson	Gentiva Health Services	41	1/10/83	1,482	1,380	1,203	157
47182	Knox	Gentiva Health Services 2 (Girling Health Care)	149	8/15/84	1,031	1,467	1,815	1
94074	Williamson	Guardian Home Care of Nashville, LLC	607	5/24/01	1,365	1,370	1,668	91
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	399	363	408	2
02024	Bedford	Heritage Home Health	4	5/4/84	280	241	421	6
71014	Putnam	Highland Rim Home Health Agency	197	5/2/78	495	574	497	493
80064	Smith	Highpoint HomeCare (Sumner HomeCare)	245	9/7/84	280	377	432	299
83114	Sumner	Highpoint HomeCare (Sumner HomeCare)	258	9/7/84	738	855	816	47
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	2,080	1,930	1,689	280
06063	Bradley	Home Health Care of East Tennessee, Inc	14	3/14/84	4,755	3,318	2,680	68
19584	Davidson	Home Health Care of Middle Tennessee	46	12/20/82	3,914	2,963	2,975	31
19364	Davidson	Intrepid USA Healthcare Services	34	6/20/84	920	766	1,389	5
71084	Putnam	Intrepid USA Healthcare Services	198	6/19/84	341	327	281	281
89064	Warren	Intrepid USA Healthcare Services	263	8/1/84	159	822	804	55
52044	Lincoln	Lincoln Medical Home Health & Hospice	160	11/22/83	396	348	339	336
60044	Maury	Maury Regional Home Services	180	5/31/84	1,220	1,151	1,553	350
33253	Hamilton	Memorial Hospital Home Health	103	8/9/82	3,264	2,439	2,651	0
33033	Hamilton	NHC HomeCare	111	6/10/77	203	354	411	0
60024	Maury	NHC HomeCare	181	11/22/77	2,134	2,408	2,591	1,289
74054	Robertson	NHC HomeCare	205	1/12/84	909	1,332	1,842	0

Table Eight: Patients Served By Home Health Agencies Licensed in Alere Davidson's Proposed Counties

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2012 JAR Total Patients Served in TN	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2014 Total Patients Served in Alere's Proposed 22-County Service Area
75024	Rutherford	NHC Homecare	208	5/17/76	3,269	3,776	4,180	1,406
60084	Maury	Quality First Home Care	90	8/12/82	855	923	1,023	667
25044	Fentress	Quality Home Health	287	3/7/84	4,012	3,404	3,591	1,704
25034	Fentress	Quality Private Duty Care	80	10/28/83	703	879	894	705
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	616	569	582	0
41034	Hickman	St. Thomas Home Health (Hickman Co. HH)	125	6/1/84	134	214	311	47
16034	Coffee	Suncrest Home Health	29	4/16/84	1,114	1,588	2,122	258
19324	Davidson	Suncrest Home Health	70	5/30/84	6,710	5,490	4,624	318
21024	DeKalb	Suncrest Home Health	60	5/28/82	1,501	1,568	2,485	1,396
63044	Montgomery	Suncrest Home Health of Nashville, Inc.	293	2/1/84	381	587	1,276	36
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	1,128	1,164	1,173	287
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	1,082	1,080	988	116
32122	Hamblen	Univ. of TN Med. Ctr Home Health/Hospice Service	153	12/18/84	1,244	1,327	751	0
19394	Davidson	Vanderbilt Community & Home Services	43	6/8/84	1,230	1,879	1,700	0
94084	Williamson	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	604	9/15/00	86	67	135	10
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	3,027	3,041	2,995	53
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	1,503	1,534	1,797	146
19694	Davidson	Willowbrook Home Health Care Agency	259	10/29/81	2,149	1,565	1,283	9
TOTALS					96,036	99,396	100,882	18,364

Source: TDH; 2014 Joint Annual Reports of Home Health Agencies

**Table Nine-A: 2014 TennCare Payor Mix of Home Health Agencies Licensed in Alere's Proposed Counties
BY AGENCY NAME**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	2014 Total Gross Revenues	2014 TennCare Gross Revenues	2014 TennCare Percent of Total Gross Revenues
26054	Franklin	Amedisys Home Care	\$3,590,072	\$0	0.0%
33103	Hamilton	Amedisys Home Health	\$9,877,048	\$0	0.0%
67024	Overton	Amedisys Home Health	\$4,345,087	\$0	0.0%
75054	Rutherford	Amedisys Home Health	\$1,763,304	\$0	0.0%
19674	Davidson	Amedisys Home Health (Cumberland Bend)	\$10,016,271	\$0	0.0%
19024	Davidson	Amedisys Home Health (Glen Echo Rd)	\$4,995,813	\$3,972,170	79.5%
47202	Knox	Amedisys Home Health Care	\$16,836,113	\$0	0.0%
75064	Rutherford	Amedisys Home Health Care	\$5,109,967	\$0	0.0%
19684	Davidson	Amedisys Home Health Services	\$544,183	\$0	0.0%
95084	Wilson	American National Home Health (Friendship)	\$3,529,063	\$0	0.0%
19714	Davidson	Angel Private Duty and Home Health, Inc. (Friendship)	\$2,128,857	\$2,097,240	98.5%
09065	Carroll	Baptist Memorial Home Care & Hospice	\$807,380	\$0	0.0%
19504	Davidson	Brookdale Home Health Nashville (Innovative Senior)	\$3,818,800	\$0	0.0%
47062	Knox	Camellia Home Health of East Tennessee	\$18,455,024	\$9,251,718	50.1%
19724	Davidson	Careall	\$8,791,208	\$2,768,953	31.5%
89074	Warren	Careall Home Care Services	\$3,215,767	\$343,134	10.7%
92025	Weakley	Careall HomeCare Services	\$15,132,242	\$5,595,861	37.0%
60074	Maury	Careall HomeCare Services	\$2,784,544	\$485,997	17.5%
26024	Franklin	Caresouth HHA Holdings of Winchester, LLC	\$11,021,653	\$0	0.0%
33383	Hamilton	Continuicare Healthservices, Inc II	\$25,062	\$0	0.0%
19734	Davidson	Coram CVS Specialty Infusion Services	\$176,267	\$0	0.0%
47402	Knox	Covenant HomeCare	\$14,925,332	\$68,948	0.5%
14024	Clay	Cumberland River HomeCare	\$5,826,358	\$4,271,182	73.3%
95034	Wilson	Deaconess HomeCare (Cedar Creek HH Care)	\$3,995,262	\$797,135	20.0%
52024	Lincoln	Deaconess HomeCare (Elk Valley)	\$2,830,159	\$465,409	16.4%
76032	Scott	Deaconess HomeCare (Elk Valley)	\$1,877,380	\$172,609	9.2%
36025	Hardin	Deaconess HomeCare (Gericare, LLC)	\$6,762,137	\$1,021,238	15.1%
19494	Davidson	Elk Valley Health Services Inc	\$27,548,490	\$17,659,060	64.1%
19614	Davidson	Friendship Home Health Agency	\$2,116,650	\$239,091	11.3%
89084	Warren	Friendship Home Health, Inc.	\$3,994,546	\$38,264	1.0%
63034	Montgomery	Gateway Home Health Clarksville	\$1,428,183	\$216,376	15.2%
16024	Coffee	Gentiva Health Services	\$1,297,209	\$0	0.0%
19084	Davidson	Gentiva Health Services	\$3,732,503	\$0	0.0%
33093	Hamilton	Gentiva Health Services	\$1,493,248	\$0	0.0%
95074	Wilson	Gentiva Health Services	\$4,792,018	\$0	0.0%
47182	Knox	Gentiva Health Services 2 (Girling Health Care)	\$9,636,209	\$0	0.0%
94074	Williamson	Guardian Home Care of Nashville, LLC	\$7,506,235	\$0	0.0%
40075	Henry	Henry County Medical Center Home Health	\$832,451	\$21,946	2.6%
02024	Bedford	Heritage Home Health	\$1,108,827	\$19,623	1.8%
71014	Putnam	Highland Rim Home Health Agency	\$5,082,566	\$3,143,679	61.9%
83114	Sumner	Highpoint HomeCare (Sumner HomeCare)	\$2,396,992	\$175,465	7.3%
80064	Smith	Highpoint HomeCare (Sumner HomeCare)	\$1,360,954	\$74,952	5.5%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	\$10,299,102	\$0	0.0%
06063	Bradley	Home Health Care of East Tennessee, Inc	\$21,171,043	\$8,574,927	40.5%
19584	Davidson	Home Health Care of Middle Tennessee	\$28,313,819	\$19,475,087	68.8%
71084	Putnam	Intrepid USA Healthcare Services	\$1,302,488	\$858	0.1%

**Table Nine-A: 2014 TennCare Payor Mix of Home Health Agencies Licensed in Alere's Proposed Counties
BY AGENCY NAME**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	2014 Total Gross Revenues	2014 TennCare Gross Revenues	2014 TennCare Percent of Total Gross Revenues
19364	Davidson	Intrepid USA Healthcare Services	\$3,330,559	\$0	0.0%
89064	Warren	Intrepid USA Healthcare Services	\$3,843,242	\$0	0.0%
52044	Lincoln	Lincoln Medical Home Health & Hospice	\$744,270	\$12,312	1.7%
60044	Maury	Maury Regional Home Services	\$3,638,674	\$266,219	7.3%
33253	Hamilton	Memorial Hospital Home Health	\$8,425,494	\$271,515	3.2%
33033	Hamilton	NHC Homecare	\$1,456,891	\$0	0.0%
60024	Maury	NHC Homecare	\$11,197,577	\$0	0.0%
74054	Robertson	NHC Homecare	\$8,054,475	\$0	0.0%
75024	Rutherford	NHC Homecare	\$16,844,138	\$0	0.0%
60084	Maury	Quality First Home Care	\$6,254,954	\$2,779,387	44.4%
25044	Fentress	Quality Home Health	\$30,808,782	\$8,163,845	26.5%
25034	Fentress	Quality Private Duty Care	\$14,826,186	\$7,965,559	53.7%
39035	Henderson	Regional Home Care - Lexington	\$2,938,591	\$21,814	0.7%
41034	Hickman	St. Thomas Home Health (Hickman Co. HH)	\$580,395	\$40,549	7.0%
21024	DeKalb	Suncrest Home Health	\$14,847,210	\$2,687,799	18.1%
19324	Davidson	Suncrest Home Health	\$19,986,741	\$3,420,006	17.1%
16034	Coffee	Suncrest Home Health	\$12,148,603	\$1,634,449	13.5%
63044	Montgomery	Suncrest Home Health of Nashville, Inc.	\$4,210,906	\$344,074	8.2%
03025	Benton	Tennessee Quality Homecare - Northwest	\$4,825,810	\$368,553	7.6%
20045	Decatur	Tennessee Quality Homecare - Southwest	\$4,205,081	\$952,819	22.7%
32122	Hamblen	Univ. of TN Med. Ctr Home Health/Hospice Service	\$5,548,831	\$37,298	0.7%
19394	Davidson	Vanderbilt Community & Home Services	\$4,178,361	\$2,468,421	59.1%
94084	Williamson	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	\$59,437	\$18,888	31.8%
27085	Gibson	Volunteer Home Care, Inc	\$12,326,672	\$2,505,219	20.3%
20055	Decatur	Volunteer Homecare of West Tennessee	\$10,485,470	\$3,632,117	34.6%
19694	Davidson	Willowbrook Home Health Care Agency	\$5,730,667	\$0	0.0%
AREAWIDE TOTALS			\$510,091,903	\$118,541,765	23.2%

**Table Nine-B: 2014 TennCare Payor Mix of Home Health Agencies Licensed in Alere's Proposed Counties
BY RANKING**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	2014 Total Gross Revenues	2014 TennCare Gross Revenues	2014 TennCare Percent of Total Gross Revenues
19714	Davidson	Angel Private Duty and Home Health, Inc. (Friendship)	\$2,128,857	\$2,097,240	98.5%
19024	Davidson	Amedisys Home Health (Glen Echo Rd)	\$4,995,813	\$3,972,170	79.5%
14024	Clay	Cumberland River Homecare	\$5,826,358	\$4,271,182	73.3%
19584	Davidson	Home Health Care of Middle Tennessee	\$28,313,819	\$19,475,087	68.8%
19494	Davidson	Elk Valley Health Services Inc	\$27,548,490	\$17,659,060	64.1%
71014	Putnam	Highland Rim Home Health Agency	\$5,082,566	\$3,143,679	61.9%
19394	Davidson	Vanderbilt Community & Home Services	\$4,178,361	\$2,468,421	59.1%
25034	Fentress	Quality Private Duty Care	\$14,826,186	\$7,965,559	53.7%
47062	Knox	Camellia Home Health of East Tennessee	\$18,455,024	\$9,251,718	50.1%
60084	Maury	Quality First Home Care	\$6,254,954	\$2,779,387	44.4%
06063	Bradley	Home Health Care of East Tennessee, Inc	\$21,171,043	\$8,574,927	40.5%
92025	Weakley	Careall Homecare Services	\$15,132,242	\$5,595,861	37.0%
20055	Decatur	Volunteer Homecare of West Tennessee	\$10,485,470	\$3,632,117	34.6%
94084	Williamson	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	\$59,437	\$18,888	31.8%
19724	Davidson	Careall	\$8,791,208	\$2,768,953	31.5%
25044	Fentress	Quality Home Health	\$30,808,782	\$8,163,845	26.5%
20045	Decatur	Tennessee Quality Homecare - Southwest	\$4,205,081	\$952,819	22.7%
27085	Gibson	Volunteer Home Care, Inc	\$12,326,672	\$2,505,219	20.3%
95034	Wilson	Deaconess Homecare (Cedar Creek HH Care)	\$3,995,262	\$797,135	20.0%
21024	DeKalb	Suncrest Home Health	\$14,847,210	\$2,687,799	18.1%
60074	Maury	Careall Homecare Services	\$2,784,544	\$485,997	17.5%
19324	Davidson	Suncrest Home Health	\$19,986,741	\$3,420,006	17.1%
52024	Lincoln	Deaconess Homecare (Elk Valley)	\$2,830,159	\$465,409	16.4%
63034	Montgomery	Gateway Home Health Clarksville	\$1,428,183	\$216,376	15.2%
36025	Hardin	Deaconess Homecare (Gericare, LLC)	\$6,762,137	\$1,021,238	15.1%
16034	Coffee	Suncrest Home Health	\$12,148,603	\$1,634,449	13.5%
19614	Davidson	Friendship Home Health Agency	\$2,116,650	\$239,091	11.3%
89074	Warren	Careall Home Care Services	\$3,215,767	\$343,134	10.7%
76032	Scott	Deaconess Homecare (Elk Valley)	\$1,877,380	\$172,609	9.2%
63044	Montgomery	Suncrest Home Health of Nashville, Inc.	\$4,210,906	\$344,074	8.2%
03025	Benton	Tennessee Quality Homecare - Northwest	\$4,825,810	\$368,553	7.6%
83114	Sumner	Highpoint Homecare (Sumner Homecare)	\$2,396,992	\$175,465	7.3%
60044	Maury	Maury Regional Home Services	\$3,638,674	\$266,219	7.3%
41034	Hickman	St. Thomas Home Health (Hickman Co. HH)	\$580,395	\$40,549	7.0%
80064	Smith	Highpoint Homecare (Sumner Homecare)	\$1,360,954	\$74,952	5.5%
33253	Hamilton	Memorial Hospital Home Health	\$8,425,494	\$271,515	3.2%
40075	Henry	Henry County Medical Center Home Health	\$832,451	\$21,946	2.6%
02024	Bedford	Heritage Home Health	\$1,108,827	\$19,623	1.8%
52044	Lincoln	Lincoln Medical Home Health & Hospice	\$744,270	\$12,312	1.7%
89084	Warren	Friendship Home Health, Inc.	\$3,994,546	\$38,264	1.0%
39035	Henderson	Regional Home Care - Lexington	\$2,938,591	\$21,814	0.7%
32122	Hamblen	Univ. of TN Med. Ctr Home Health/Hospice Service	\$5,548,831	\$37,298	0.7%
47402	Knox	Covenant Homecare	\$14,925,332	\$68,948	0.5%
71084	Putnam	Intrepid USA Healthcare Services	\$1,302,488	\$858	0.1%
26054	Franklin	Amedisys Home Care	\$3,590,072	\$0	0.0%
33103	Hamilton	Amedisys Home Health	\$9,877,048	\$0	0.0%

**Table Nine-B: 2014 TennCare Payor Mix of Home Health Agencies Licensed in Alere's Proposed Counties
BY RANKING**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	2014 Total Gross Revenues	2014 TennCare Gross Revenues	2014 TennCare Percent of Total Gross Revenues
67024	Overton	Amedisys Home Health	\$4,345,087	\$0	0.0%
75054	Rutherford	Amedisys Home Health	\$1,763,304	\$0	0.0%
19674	Davidson	Amedisys Home Health (Cumberland Bend)	\$10,016,271	\$0	0.0%
47202	Knox	Amedisys Home Health Care	\$16,836,113	\$0	0.0%
75064	Rutherford	Amedisys Home Health Care	\$5,109,967	\$0	0.0%
19684	Davidson	Amedisys Home Health Services	\$544,183	\$0	0.0%
95084	Wilson	American National Home Health (Friendship)	\$3,529,063	\$0	0.0%
09065	Carroll	Baptist Memorial Home Care & Hospice	\$807,380	\$0	0.0%
19504	Davidson	Brookdale Home Health Nashville (Innovative Senior)	\$3,818,800	\$0	0.0%
26024	Franklin	Caresouth HHA Holdings of Winchester, LLC	\$11,021,653	\$0	0.0%
33383	Hamilton	Continuicare Healthservices, Inc II	\$25,062	\$0	0.0%
19734	Davidson	Coram CVS Specialty Infusion Services	\$176,267	\$0	0.0%
16024	Coffee	Gentiva Health Services	\$1,297,209	\$0	0.0%
19084	Davidson	Gentiva Health Services	\$3,732,503	\$0	0.0%
33093	Hamilton	Gentiva Health Services	\$1,493,248	\$0	0.0%
95074	Wilson	Gentiva Health Services	\$4,792,018	\$0	0.0%
47182	Knox	Gentiva Health Services 2 (Girling Health Care)	\$9,636,209	\$0	0.0%
94074	Williamson	Guardian Home Care of Nashville, LLC	\$7,506,235	\$0	0.0%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	\$10,299,102	\$0	0.0%
19364	Davidson	Intrepid USA Healthcare Services	\$3,330,559	\$0	0.0%
89064	Warren	Intrepid USA Healthcare Services	\$3,843,242	\$0	0.0%
33033	Hamilton	NHC Homecare	\$1,456,891	\$0	0.0%
60024	Maury	NHC Homecare	\$11,197,577	\$0	0.0%
74054	Robertson	NHC Homecare	\$8,054,475	\$0	0.0%
75024	Rutherford	NHC Homecare	\$16,844,138	\$0	0.0%
19694	Davidson	Willowbrook Home Health Care Agency	\$5,730,667	\$0	0.0%
AREAWIDE TOTALS			\$510,091,903	\$118,541,765	23.2%

**Table Ten-A: 2014 Agency Dependence on Female Patients 18-64
in Alere's 22 Proposed Counties--BY AGENCY**

TDH ID	AGENCY NAME	Total Agency Patients in TN	Total Agency Patients From Alere's Proposed Counties	Percent of Agency Dependence on Patients in Alere's Proposed Counties	Percent of Agency Dependence on Female Age 18-64 Patients in Alere's Proposed Counties
26054	Amedisys Home Care	1,002	590	58.9%	5.8%
33103	Amedisys Home Health	2,564	17	0.7%	8.8%
19674	Amedisys Home Health (Cumberland Bend)	2,148	207	9.6%	7.0%
19024	Amedisys Home Health (Glen Echo Rd)	1,508	40	2.7%	16.3%
67024	Amedisys Home Health (Overton)	949	878	92.5%	8.8%
75054	Amedisys Home Health (Rutherford)	535	14	2.6%	14.3%
75064	Amedisys Home Health Care	1,372	388	28.3%	9.1%
47202	Amedisys Home Health Care	4,391	1	0.0%	0.0%
19684	Amedisys Home Health Services	210	0	0.0%	0.0%
95084	American National Home Health (Quality)	305	77	25.2%	12.3%
19714	Angel Private Duty and Home Health, Inc. (Friendship)	79	10	12.7%	25.0%
09065	Baptist Memorial Home Care & Hospice	283	6	2.1%	25.0%
19504	Brookdale Home Health Nashville (Innovative Senior)	587	0	0.0%	0.0%
47062	Camellia Home Health of East Tennessee	1,732	127	7.3%	5.5%
19724	Careall	1,665	937	56.3%	11.3%
89074	Careall Home Care Services	974	290	29.8%	9.3%
60074	Careall HomeCare Services	881	415	47.1%	14.5%
92025	Careall HomeCare Services	2,337	87	3.7%	15.5%
26024	Caresouth HHA Holdings of Winchester, LLC	2,444	522	21.4%	10.9%
33383	Continuicare Healthservices, Inc II	7	0	0.0%	0.0%
19734	Coram CVS Specialty Infusion Services	26	2	7.7%	25.0%
47402	Covenant HomeCare	4,792	0	0.0%	0.0%
14024	Cumberland River HomeCare	393	393	100.0%	12.5%
95034	Deaconess HomeCare (Cedar Creek HH Care)	1,706	597	35.0%	19.6%
52024	Deaconess HomeCare (Elk Valley)	1,294	778	60.1%	16.9%
76032	Deaconess HomeCare (Elk Valley)	603	35	5.8%	14.3%
36025	Deaconess HomeCare (Gericare, LLC)	2,122	183	8.6%	21.9%
19494	Elk Valley Health Services Inc	293	51	17.4%	24.5%
19614	Friendship Home Health Agency	745	4	0.5%	12.5%
89084	Friendship Home Health, Inc.	1,721	610	35.4%	6.6%
63034	Gateway Home Health Clarksville	1,340	80	6.0%	18.1%
16024	Gentiva Health Services	320	76	23.8%	11.8%
95074	Gentiva Health Services	1,203	157	13.1%	11.5%
19084	Gentiva Health Services	831	0	0.0%	0.0%
33093	Gentiva Health Services	348	0	0.0%	0.0%
47182	Gentiva Health Services 2 (Girling Health Care)	1,815	1	0.1%	0.0%
94074	Guardian Home Care of Nashville, LLC	1,668	91	5.5%	12.1%
40075	Henry County Medical Center Home Health	408	2	0.5%	50.0%
02024	Heritage Home Health	421	6	1.4%	50.0%
71014	Highland Rim Home Health Agency	497	493	99.2%	11.3%
80064	Highpoint HomeCare (Sumner HomeCare)	432	299	69.2%	13.9%
83114	Highpoint HomeCare (Sumner HomeCare)	816	47	5.8%	11.7%
19544	Home Care Solutions, Inc (LHC HomeCare of TN)	1,689	280	16.6%	7.0%
06063	Home Health Care of East Tennessee, Inc	2,680	68	2.5%	16.9%
19584	Home Health Care of Middle Tennessee	2,975	31	1.0%	21.0%
71084	Intrepid USA Healthcare Services	281	281	100.0%	9.4%
89064	Intrepid USA Healthcare Services	804	55	6.8%	11.8%
19364	Intrepid USA Healthcare Services	1,389	5	0.4%	30.0%

**Table Ten-A: 2014 Agency Dependence on Female Patients 18-64
in Alere's 22 Proposed Counties--BY AGENCY**

TDH ID	AGENCY NAME	Total Agency Patients in TN	Total Agency Patients From Alere's Proposed Counties	Percent of Agency Dependence on Patients in Alere's Proposed Counties	Percent of Agency Dependence on Female Age 18-64 Patients in Alere's Proposed Counties
52044	Lincoln Medical Home Health & Hospice	339	336	99.1%	9.7%
60044	Maury Regional Home Services	1,553	350	22.5%	21.3%
33253	Memorial Hospital Home Health	2,651	0	0.0%	0.0%
60024	NHC Homecare	2,591	1,289	49.7%	11.8%
75024	NHC Homecare	4,180	1,406	33.6%	11.1%
33033	NHC Homecare	411	0	0.0%	0.0%
74054	NHC Homecare	1,842	0	0.0%	0.0%
60084	Quality First Home Care	1,023	667	65.2%	14.8%
25044	Quality Home Health	3,591	1,704	47.5%	15.7%
25034	Quality Private Duty Care	894	705	78.9%	18.6%
39035	Regional Home Care - Lexington	582	0	0.0%	0.0%
41034	St. Thomas Home Health (Hickman Co. HH)	311	47	15.1%	7.4%
21024	Suncrest Home Health	2,485	1,396	56.2%	13.0%
16034	Suncrest Home Health	2,122	258	12.2%	17.8%
19324	Suncrest Home Health	4,624	318	6.9%	16.7%
63044	Suncrest Home Health of Nashville, Inc.	1,276	36	2.8%	31.9%
03025	Tennessee Quality Homecare - Northwest	1,173	287	24.5%	11.5%
20045	Tennessee Quality Homecare - Southwest	988	116	11.7%	9.5%
32122	Univ. of TN Med. Ctr Home Health (Morristown)	751	0	0.0%	0.0%
19394	Vanderbilt Community & Home Services	1,700	0	0.0%	0.0%
94084	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	135	10	7.4%	45.0%
27085	Volunteer Home Care, Inc	2,995	53	1.8%	23.6%
20055	Volunteer Homecare of West Tennessee	1,797	146	8.1%	9.9%
19694	Willowbrook Home Health Care Agency	1,283	9	0.7%	16.7%
		100,882	18,364	18.2%	12.9%

**Table Ten-B: 2014 Agency Dependence on Alere's 22 Proposed Counties
BY RANKING OF ALL PATIENTS FROM THAT AREA**

TDH ID	AGENCY NAME	Total Agency Patients in TN	Total Agency Patients From Alere's Proposed Counties	Percent of Agency Dependence on Patients in Alere's Proposed Counties	Percent of Agency Dependence on Female Age 18-64 Patients in Alere's Proposed Counties
71084	Intrepid USA Healthcare Services	281	281	100.0%	9.4%
14024	Cumberland River Homecare	393	393	100.0%	12.5%
71014	Highland Rim Home Health Agency	497	493	99.2%	11.3%
52044	Lincoln Medical Home Health & Hospice	339	336	99.1%	9.7%
67024	Amedisys Home Health (Overton)	949	878	92.5%	8.8%
25034	Quality Private Duty Care	894	705	78.9%	18.6%
80064	Highpoint Homecare (Sumner Homecare)	432	299	69.2%	13.9%
60084	Quality First Home Care	1,023	667	65.2%	14.8%
52024	Deaconess Homecare (Elk Valley)	1,294	778	60.1%	16.9%
26054	Amedisys Home Care	1,002	590	58.9%	5.8%
19724	Careall	1,665	937	56.3%	11.3%
21024	Suncrest Home Health	2,485	1,396	56.2%	13.0%
60024	NHC Homecare	2,591	1,289	49.7%	11.8%
25044	Quality Home Health	3,591	1,704	47.5%	15.7%
60074	Careall Homecare Services	881	415	47.1%	14.5%
89084	Friendship Home Health, Inc.	1,721	610	35.4%	6.6%
95034	Deaconess Homecare (Cedar Creek HH Care)	1,706	597	35.0%	19.6%
75024	NHC Homecare	4,180	1,406	33.6%	11.1%
89074	Careall Home Care Services	974	290	29.8%	9.3%
75064	Amedisys Home Health Care	1,372	388	28.3%	9.1%
95084	American National Home Health (Quality)	305	77	25.2%	12.3%
03025	Tennessee Quality Homecare - Northwest	1,173	287	24.5%	11.5%
16024	Gentiva Health Services	320	76	23.8%	11.8%
60044	Maury Regional Home Services	1,553	350	22.5%	21.3%
26024	Caresouth HHA Holdings of Winchester, LLC	2,444	522	21.4%	10.9%
19494	Elk Valley Health Services Inc	293	51	17.4%	24.5%
19544	Home Care Solutions, Inc (LHC HomeCare of TN)	1,689	280	16.6%	7.0%
41034	St. Thomas Home Health (Hickman Co. HH)	311	47	15.1%	7.4%
95074	Gentiva Health Services	1,203	157	13.1%	11.5%
19714	Angel Private Duty and Home Health, Inc. (Friendship)	79	10	12.7%	25.0%
16034	Suncrest Home Health	2,122	258	12.2%	17.8%
20045	Tennessee Quality Homecare - Southwest	988	116	11.7%	9.5%
19674	Amedisys Home Health (Cumberland Bend)	2,148	207	9.6%	7.0%
36025	Deaconess Homecare (Gericare, LLC)	2,122	183	8.6%	21.9%
20055	Volunteer Homecare of West Tennessee	1,797	146	8.1%	9.9%
19734	Coram CVS Specialty Infusion Services	26	2	7.7%	25.0%
94084	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	135	10	7.4%	45.0%
47062	Camellia Home Health of East Tennessee	1,732	127	7.3%	5.5%
19324	Suncrest Home Health	4,624	318	6.9%	16.7%
89064	Intrepid USA Healthcare Services	804	55	6.8%	11.8%
63034	Gateway Home Health Clarksville	1,340	80	6.0%	18.1%
76032	Deaconess Homecare (Elk Valley)	603	35	5.8%	14.3%
83114	Highpoint Homecare (Sumner Homecare)	816	47	5.8%	11.7%
94074	Guardian Home Care of Nashville, LLC	1,668	91	5.5%	12.1%
92025	Careall Homecare Services	2,337	87	3.7%	15.5%
63044	Suncrest Home Health of Nashville, Inc.	1,276	36	2.8%	31.9%
19024	Amedisys Home Health (Glen Echo Rd)	1,508	40	2.7%	16.3%
75054	Amedisys Home Health (Rutherford)	535	14	2.6%	14.3%

**Table Ten-B: 2014 Agency Dependence on Alere's 22 Proposed Counties
BY RANKING OF ALL PATIENTS FROM THAT AREA**

TDH ID	AGENCY NAME	Total Agency Patients in TN	Total Agency Patients From Alere's Proposed Counties	Percent of Agency Dependence on Patients in Alere's Proposed Counties	Percent of Agency Dependence on Female Age 18-64 Patients in Alere's Proposed Counties
06063	Home Health Care of East Tennessee, Inc	2,680	68	2.5%	16.9%
09065	Baptist Memorial Home Care & Hospice	283	6	2.1%	25.0%
27085	Volunteer Home Care, Inc	2,995	53	1.8%	23.6%
02024	Heritage Home Health	421	6	1.4%	50.0%
19584	Home Health Care of Middle Tennessee	2,975	31	1.0%	21.0%
19694	Willowbrook Home Health Care Agency	1,283	9	0.7%	16.7%
33103	Amedisys Home Health	2,564	17	0.7%	8.8%
19614	Friendship Home Health Agency	745	4	0.5%	12.5%
40075	Henry County Medical Center Home Health	408	2	0.5%	50.0%
19364	Intrepid USA Healthcare Services	1,389	5	0.4%	30.0%
47182	Gentiva Health Services 2 (Girling Health Care)	1,815	1	0.1%	0.0%
47202	Amedisys Home Health Care	4,391	1	0.0%	0.0%
19684	Amedisys Home Health Services	210	0	0.0%	0.0%
19504	Brookdale Home Health Nashville (Innovative Senior)	587	0	0.0%	0.0%
33383	Continuicare Healthservices, Inc II	7	0	0.0%	0.0%
47402	Covenant Homecare	4,792	0	0.0%	0.0%
19084	Gentiva Health Services	831	0	0.0%	0.0%
33093	Gentiva Health Services	348	0	0.0%	0.0%
33253	Memorial Hospital Home Health	2,651	0	0.0%	0.0%
33033	NHC Homecare	411	0	0.0%	0.0%
74054	NHC Homecare	1,842	0	0.0%	0.0%
39035	Regional Home Care - Lexington	582	0	0.0%	0.0%
32122	Univ. of TN Med. Ctr Home Health (Morristown)	751	0	0.0%	0.0%
19394	Vanderbilt Community & Home Services	1,700	0	0.0%	0.0%
		100,882	18,364	18.2%	12.9%

**Table Ten-C: 2014 Agency Dependence on Alere's Proposed Counties
BY RANKING OF ITS FEMALE AGE 18-64 PATIENTS FROM THAT AREA**

TDH ID	AGENCY NAME	Total Agency Patients in TN	Total Agency Patients From Alere's Proposed Counties	Percent of Agency Dependence on Patients in Alere's Proposed Counties	Percent of Agency Dependence on Female Age 18-64 Patients in Alere's Proposed Counties
40075	Henry County Medical Center Home Health	408	2	0.5%	50.0%
02024	Heritage Home Health	421	6	1.4%	50.0%
94084	Vanderbilt HC Affiliated w/Walgreens IV & RT Svcs	135	10	7.4%	45.0%
63044	Suncrest Home Health of Nashville, Inc.	1,276	36	2.8%	31.9%
19364	Intrepid USA Healthcare Services	1,389	5	0.4%	30.0%
19714	Angel Private Duty and Home Health, Inc. (Friendship)	79	10	12.7%	25.0%
09065	Baptist Memorial Home Care & Hospice	283	6	2.1%	25.0%
19734	Coram CVS Specialty Infusion Services	26	2	7.7%	25.0%
19494	Elk Valley Health Services Inc	293	51	17.4%	24.5%
27085	Volunteer Home Care, Inc	2,995	53	1.8%	23.6%
36025	Deaconess Homecare (Gericare, LLC)	2,122	183	8.6%	21.9%
60044	Maury Regional Home Services	1,553	350	22.5%	21.3%
19584	Home Health Care of Middle Tennessee	2,975	31	1.0%	21.0%
95034	Deaconess Homecare (Cedar Creek HH Care)	1,706	597	35.0%	19.6%
25034	Quality Private Duty Care	894	705	78.9%	18.6%
63034	Gateway Home Health Clarksville	1,340	80	6.0%	18.1%
16034	Suncrest Home Health	2,122	258	12.2%	17.8%
06063	Home Health Care of East Tennessee, Inc	2,680	68	2.5%	16.9%
52024	Deaconess Homecare (Elk Valley)	1,294	778	60.1%	16.9%
19324	Suncrest Home Health	4,624	318	6.9%	16.7%
19694	Willowbrook Home Health Care Agency	1,283	9	0.7%	16.7%
19024	Amedisys Home Health (Glen Echo Rd)	1,508	40	2.7%	16.3%
25044	Quality Home Health	3,591	1,704	47.5%	15.7%
92025	Careall Homecare Services	2,337	87	3.7%	15.5%
60084	Quality First Home Care	1,023	667	65.2%	14.8%
60074	Careall Homecare Services	881	415	47.1%	14.5%
75054	Amedisys Home Health (Rutherford)	535	14	2.6%	14.3%
76032	Deaconess Homecare (Elk Valley)	603	35	5.8%	14.3%
80064	Highpoint Homecare (Sumner Homecare)	432	299	69.2%	13.9%
21024	Suncrest Home Health	2,485	1,396	56.2%	13.0%
19614	Friendship Home Health Agency	745	4	0.5%	12.5%
14024	Cumberland River Homecare	393	393	100.0%	12.5%
95084	American National Home Health (Quality)	305	77	25.2%	12.3%
94074	Guardian Home Care of Nashville, LLC	1,668	91	5.5%	12.1%
16024	Gentiva Health Services	320	76	23.8%	11.8%
60024	NHC Homecare	2,591	1,289	49.7%	11.8%
89064	Intrepid USA Healthcare Services	804	55	6.8%	11.8%
83114	Highpoint Homecare (Sumner Homecare)	816	47	5.8%	11.7%
03025	Tennessee Quality Homecare - Northwest	1,173	287	24.5%	11.5%
95074	Gentiva Health Services	1,203	157	13.1%	11.5%
19724	Careall	1,665	937	56.3%	11.3%
71014	Highland Rim Home Health Agency	497	493	99.2%	11.3%
75024	NHC Homecare	4,180	1,406	33.6%	11.1%
26024	Caresouth HHA Holdings of Winchester, LLC	2,444	522	21.4%	10.9%
20055	Volunteer Homecare of West Tennessee	1,797	146	8.1%	9.9%
52044	Lincoln Medical Home Health & Hospice	339	336	99.1%	9.7%
20045	Tennessee Quality Homecare - Southwest	988	116	11.7%	9.5%
71084	Intrepid USA Healthcare Services	281	281	100.0%	9.4%

**Table Ten-C: 2014 Agency Dependence on Alere's Proposed Counties
BY RANKING OF ITS FEMALE AGE 18-64 PATIENTS FROM THAT AREA**

TDH ID	AGENCY NAME	Total Agency Patients in TN	Total Agency Patients From Alere's Proposed Counties	Percent of Agency Dependence on Patients in Alere's Proposed Counties	Percent of Agency Dependence on Female Age 18-64 Patients in Alere's Proposed Counties
89074	Careall Home Care Services	974	290	29.8%	9.3%
75064	Amedisys Home Health Care	1,372	388	28.3%	9.1%
33103	Amedisys Home Health	2,564	17	0.7%	8.8%
67024	Amedisys Home Health (Overton)	949	878	92.5%	8.8%
41034	St. Thomas Home Health (Hickman Co. HH)	311	47	15.1%	7.4%
19674	Amedisys Home Health (Cumberland Bend)	2,148	207	9.6%	7.0%
19544	Home Care Solutions, Inc (LHC HomeCare of TN)	1,689	280	16.6%	7.0%
89084	Friendship Home Health, Inc.	1,721	610	35.4%	6.6%
26054	Amedisys Home Care	1,002	590	58.9%	5.8%
47062	Camellia Home Health of East Tennessee	1,732	127	7.3%	5.5%
47202	Amedisys Home Health Care	4,391	1	0.0%	0.0%
19684	Amedisys Home Health Services	210	0	0.0%	0.0%
19504	Brookdale Home Health Nashville (Innovative Senior)	587	0	0.0%	0.0%
33383	Continuicare Healthservices, Inc II	7	0	0.0%	0.0%
47402	Covenant Homecare	4,792	0	0.0%	0.0%
19084	Gentiva Health Services	831	0	0.0%	0.0%
33093	Gentiva Health Services	348	0	0.0%	0.0%
47182	Gentiva Health Services 2 (Girling Health Care)	1,815	1	0.1%	0.0%
33253	Memorial Hospital Home Health	2,651	0	0.0%	0.0%
33033	NHC Homecare	411	0	0.0%	0.0%
74054	NHC Homecare	1,842	0	0.0%	0.0%
39035	Regional Home Care - Lexington	582	0	0.0%	0.0%
32122	Univ. of TN Med. Ctr Home Health (Morristown)	751	0	0.0%	0.0%
19394	Vanderbilt Community & Home Services	1,700	0	0.0%	0.0%
		100,882	18,364	18.2%	12.9%

C(1).6. PROVIDE APPLICABLE UTILIZATION AND/OR OCCUPANCY STATISTICS FOR YOUR INSTITUTION FOR EACH OF THE PAST THREE (3) YEARS AND THE PROJECTED ANNUAL UTILIZATION FOR EACH OF THE TWO (2) YEARS FOLLOWING COMPLETION OF THE PROJECT. ADDITIONALLY, PROVIDE THE DETAILS REGARDING THE METHODOLOGY USED TO PROJECT UTILIZATION. THE METHODOLOGY MUST INCLUDE DETAILED CALCULATIONS OR DOCUMENTATION FROM REFERRAL SOURCES, AND IDENTIFICATION OF ALL ASSUMPTIONS.

Applicant's Historical Utilization

Following this page is Table Eleven-A, providing the past three years of utilization for Alere Women's and Children's Health in all three Tennessee home care agency locations. The second following page is Table Eleven-B, providing comprehensive statistics on the 2014 utilization of Alere Women's and Children's Health of Davidson County as reported in its 2014 Joint Annual Report.

Applicant's Projected Utilization

The applicant projected its utilization from the proposed service area using a two-step process, as stated below. The steps are reflected in Tables Twelve-A and -B, which follow the historical Alere utilization charts that begin after this page.

1. Alere/Davidson's 2014 overall use rate in its current 14-county service area was calculated. Alere's patients by county in 2014 were totaled (183) and divided by the 2014 female population of childbearing age for these 14 counties (421,818) to derive the target population's average service area use rate of Alere / Davidson, which was 0.043%. See Table Ten-A below.

2. The Agency's 2014 average use rate was then applied to the projected Years One and Two population of females of childbearing age in the proposed service area. That resulted in a projection of 41.4 and 41.9 additional Alere patients in 2016 and 2017. See Table Ten-B below.

Table Eleven-A: Alere Women's and Children's Health (All Tennessee Agencies)
2012-2014 Total Patients, 2014 TennCare Patients, 2014 Patients of Childbearing Age (18-64)

Health Statistics ID Number	Home Health Agency Name	Agency License Number	County of Parent Office	Date Agency Licensed	2012 JAR Total Patients Served	2013 JAR Total Patients Served	2014 JAR Total Patients Served	2014 JAR TennCare Patients Served	2014 TennCare Percent of Total Patients Served	2014 Patients Served Ages 18-64	2014 Percent of Total Patients Served Who were Age 18-64
19654	Alere Women's and Children's Health	471	Davidson	3/1/99	196	202	186	134	72.0%	184	98.9%
33423	Alere Women's and Children's Health	457	Hamilton	11/13/98	52	74	50	36	72.0%	50	100.0%
79466	Alere Women's and Children's Health	459	Shelby	12/21/98	401	417	376	175	46.5%	375	99.7%
Statewide Totals					649	693	612	345	56.4%	609	99.5%

Source: TDH; 2014 Joint Annual Reports of Home Health Agencies

Table Eleven-B: 2014 Alere / Davidson County Utilization

Health Statistics ID	Agency County	Agency Name	Total Patients	TNCare Patients	TnCare % of Patients
19654	Davidson	Alere Women's and Children's Health	186	134	72.0%
			Total Gross Revenue	TNCare Gross Revenue	TnCare % of Gross Revenue
			\$637,027	\$305,662	48.0%
			Total Visits	TNCare Visits	TnCare % of Visits
			1,623	1,210	74.6%
			Total Hours	TNCare Hours	TnCare % of Hours
			2,433	1,815	74.6%
			Total Patients	Patients Age 18-64	% of Patients Age 18-64
			186	134	72.0%

Source: HHA Joint Ann. Reports, 2014.

Table Twelve-A: Alere Davidson's Use Rates in 2014

County	Alere Agency's Total Patients in 2014	2014 Female Population 15-44	Alere Use Rate by Population of Childbearing Age
DAVIDSON CO. AGENCY			
Bedford	5	9,180	0.054%
Cheatham	3	7,426	0.040%
Davidson	64	148,724	0.043%
Dickson	6	9,612	0.062%
Hickman	9	4,186	0.215%
Houston	1	1,438	0.070%
Marshall	7	5,898	0.119%
Mauzy	7	15,594	0.045%
Montgomery	15	42,458	0.035%
Robertson	12	13,636	0.088%
Rutherford	27	67,986	0.040%
Sumner	18	32,982	0.055%
Williamson	4	39,543	0.010%
Wilson	5	23,155	0.022%
AGENCY TOTAL	183	421,818	0.043%

Source: Joint Annual Reports; TDH Population Projections 2013 Series.

Notes:

1. Patients exclude 3 from outside licensed service area (KY).
2. Patients include 3 patients age 0-17.

Table Twelve-B: Alere Patients By Proposed New Counties--CY2016 & CY2017

Proposed Counties To Be Added to Alere's Service Areas	2016 Female Population 15-44	2017 Female Population 15-44	Agency's 2014 Average Use Rate in Its Current Counties	2016 Projected New Alere Patients	2017 Projected New Alere Patients
DAVIDSON CO. AGENCY					
Cannon	2,593	2,632	0.043%	1.11	1.13
Clay	1,241	1,236	0.043%	0.53	0.53
Cumberland	9,607	9,920	0.043%	4.13	4.27
DeKalb	3,301	3,305	0.043%	1.42	1.42
Fentress	3,310	3,332	0.043%	1.42	1.43
Franklin	8,236	8,362	0.043%	3.54	3.60
Giles	5,144	5,129	0.043%	2.21	2.21
Humphreys	3,210	3,202	0.043%	1.38	1.38
Jackson	1,905	1,896	0.043%	0.82	0.82
Lawrence	7,519	7,490	0.043%	3.23	3.22
Lewis	2,121	2,113	0.043%	0.91	0.91
Lincoln	7,435	7,612	0.043%	3.20	3.27
Macon	4,502	4,547	0.043%	1.94	1.96
Moore	1,174	1,190	0.043%	0.50	0.51
Overton	4,111	4,112	0.043%	1.77	1.77
Pickett	727	728	0.043%	0.31	0.31
Putnam	16,530	16,799	0.043%	7.11	7.22
Smith	3,760	3,804	0.043%	1.62	1.64
Stewart	2,351	2,348	0.043%	1.01	1.01
Trousdale	1,625	1,632	0.043%	0.70	0.70
Van Buren	885	889	0.043%	0.38	0.38
White	4,959	5,046	0.043%	2.13	2.17
NEW COUNTIES TOTAL	96,246	97,324	0.043%	41.39	41.85

C(II)1. PROVIDE THE COST OF THE PROJECT BY COMPLETING THE PROJECT COSTS CHART ON THE FOLLOWING PAGE. JUSTIFY THE COST OF THE PROJECT.

- **ALL PROJECTS SHOULD HAVE A PROJECT COST OF AT LEAST \$3,000 ON LINE F (MINIMUM CON FILING FEE). CON FILING FEE SHOULD BE CALCULATED ON LINE D.**

- **THE COST OF ANY LEASE (BUILDING, LAND, AND/OR EQUIPMENT) SHOULD BE BASED ON FAIR MARKET VALUE OR THE TOTAL AMOUNT OF THE LEASE PAYMENTS OVER THE INITIAL TERM OF THE LEASE, WHICHEVER IS GREATER. NOTE: THIS APPLIES TO ALL EQUIPMENT LEASES INCLUDING BY PROCEDURE OR "PER CLICK" ARRANGEMENTS. THE METHODOLOGY USED TO DETERMINE THE TOTAL LEASE COST FOR A "PER CLICK" ARRANGEMENT MUST INCLUDE, AT A MINIMUM, THE PROJECTED PROCEDURES, THE "PER CLICK" RATE AND THE TERM OF THE LEASE.**

- **THE COST FOR FIXED AND MOVEABLE EQUIPMENT INCLUDES, BUT IS NOT NECESSARILY LIMITED TO, MAINTENANCE AGREEMENTS COVERING THE EXPECTED USEFUL LIFE OF THE EQUIPMENT; FEDERAL, STATE, AND LOCAL TAXES AND OTHER GOVERNMENT ASSESSMENTS; AND INSTALLATION CHARGES, EXCLUDING CAPITAL EXPENDITURES FOR PHYSICAL PLANT RENOVATION OR IN-WALL SHIELDING, WHICH SHOULD BE INCLUDED UNDER CONSTRUCTION COSTS OR INCORPORATED IN A FACILITY LEASE.**

- **FOR PROJECTS THAT INCLUDE NEW CONSTRUCTION, MODIFICATION, AND/OR RENOVATION; DOCUMENTATION MUST BE PROVIDED FROM A CONTRACTOR AND/OR ARCHITECT THAT SUPPORT THE ESTIMATED CONSTRUCTION COSTS.**

Please see the following page for the Project Cost Chart. There is no construction required.

PROJECT COSTS CHART--ALERE DAVIDSON COUNTY--EXPANSION

A. Construction and equipment acquired by purchase:

1. Architectural and Engineering Fees	\$	0
2. Legal, Administrative, Consultant Fees (Excl CON Filing Fee)		65,000
3. Acquisition of Site		0
4. Preparation of Site		0
5. Construction Cost		0
6. Contingency Fund		0
7. Fixed Equipment (Not included in Construction Contract)		0
8. Moveable Equipment (List all equipment over \$50,000)		16,000
9. Other (Specify) _____		0

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)		0
2. Building only		0
3. Land only		0
4. Equipment (Specify) _____		0
5. Other (Specify) _____		0

C. Financing Costs and Fees:

1. Interim Financing		0
2. Underwriting Costs		0
3. Reserve for One Year's Debt Service		0
4. Other (Specify) _____		0

D. Estimated Project Cost (A+B+C)

81,000

E. CON Filing Fee

3,000

F. Total Estimated Project Cost (D+E)

TOTAL \$ 84,000

Actual Capital Cost 84,000
Section B FMV 0

C(II).2. IDENTIFY THE FUNDING SOURCES FOR THIS PROJECT.

a. PLEASE CHECK THE APPLICABLE ITEM(S) BELOW AND BRIEFLY SUMMARIZE HOW THE PROJECT WILL BE FINANCED. (DOCUMENTATION FOR THE TYPE OF FUNDING MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND IDENTIFIED AS ATTACHMENT C, ECONOMIC FEASIBILITY--2).

☐ **A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**

☐ **B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;**

☐ **C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;**

☐ **D. Grants--Notification of Intent form for grant application or notice of grant award;**

☒ **E. Cash Reserves--Appropriate documentation from Chief Financial Officer; or**

☐ **F. Other--Identify and document funding from all sources.**

The project will be funded/financed in cash by United Health Group (UHG), the ultimate parent company of Alere Women's and Children's Health, LLC. Documentation of financing is provided in Attachment C, Economic Feasibility--2. UHG's income statement and balance sheet are also included.

C(II).3. DISCUSS AND DOCUMENT THE REASONABLENESS OF THE PROPOSED PROJECT COSTS. IF APPLICABLE, COMPARE THE COST PER SQUARE FOOT OF CONSTRUCTION TO SIMILAR PROJECTS RECENTLY APPROVED BY THE HSDA.

Not applicable; the project does not include construction.

C(II).4. COMPLETE HISTORICAL AND PROJECTED DATA CHARTS ON THE FOLLOWING TWO PAGES--DO NOT MODIFY THE CHARTS PROVIDED OR SUBMIT CHART SUBSTITUTIONS. HISTORICAL DATA CHART REPRESENTS REVENUE AND EXPENSE INFORMATION FOR THE LAST THREE (3) YEARS FOR WHICH COMPLETE DATA IS AVAILABLE FOR THE INSTITUTION. PROJECTED DATA CHART REQUESTS INFORMATION FOR THE TWO YEARS FOLLOWING COMPLETION OF THIS PROPOSAL. PROJECTED DATA CHART SHOULD INCLUDE REVENUE AND EXPENSE PROJECTIONS FOR THE PROPOSAL ONLY (I.E., IF THE APPLICATION IS FOR ADDITIONAL BEDS, INCLUDE ANTICIPATED REVENUE FROM THE PROPOSED BEDS ONLY, NOT FROM ALL BEDS IN THE FACILITY).

See the following three pages for these charts, with notes for all three charts immediately following the charts.

Alere/Davidson serves some patients outside of Tennessee, (e.g. in Kentucky)--the reason for the notation in the Patients line of the Historic Data Chart.

HISTORICAL DATA CHART -- ALERE DAVIDSON COUNTY
(ALL DATA ON CALENDAR YEAR BASIS EXCEPT LINE A FYE PATIENTS FROM JAR)

Give information for the last three (3) years for which complete data are available for the facility or agency.

The fiscal year begins in January.

		CY 2012	CY 2013	CY 2014
	CY Patients, TN & Other	238	191	200
A.	Utilization Data			
	FYE Patients, TN only (JAR)	196	202	186
B.	Revenue from Services to Patients			
1.	Inpatient Services	\$		
2.	Outpatient Services			
3.	Emergency Services			
4.	Other Operating Revenue	2,569,257	1,856,108	1,786,408
	(Specify) <u>See notes page</u>			
	Gross Operating Revenue	\$ 2,569,257	\$ 1,856,108	\$ 1,786,408
C.	Deductions for Operating Revenue			
1.	Contractual Adjustments	\$ 1,595,464	1,206,597	1,095,355
2.	Provision for Charity Care	25,693	18,561	17,864
3.	Provisions for Bad Debt	41,757	32,295	22,985
	Total Deductions	\$ 1,662,914	\$ 1,257,453	\$ 1,136,204
	NET OPERATING REVENUE	\$ 906,343	\$ 598,655	\$ 650,204
D.	Operating Expenses			
1.	Salaries and Wages	\$ 271,176	266,704	256,086
2.	Physicians Salaries and Wages			
3.	Supplies	111,065	98,080	79,870
4.	Taxes	4,442	3,950	2,890
5.	Depreciation	7,201	5,371	4,371
6.	Rent	21,600	21,600	21,600
7.	Interest, other than Capital			
8.	Management Fees			
	a. Fees to Affiliates			
	b. Fees to Non-Affiliates			
9.	Other Expenses (Specify) <u>See notes page</u>	72,891	69,052	66,009
	Total Operating Expenses	\$ 488,375	464,757	430,826
E.	Other Revenue (Expenses) -- Net (Specify)	\$	\$	\$
	NET OPERATING INCOME (LOSS)	\$ 417,968	\$ 133,898	\$ 219,378
F.	Capital Expenditures			
1.	Retirement of Principal	\$	\$	\$
2.	Interest			
	Total Capital Expenditures	\$ 0	\$ 0	\$ 0
	NET OPERATING INCOME (LOSS)			
	LESS CAPITAL EXPENDITURES	\$ 417,968	\$ 133,898	\$ 219,378

**PROJECTED DATA CHART--ALERE (DAVIDSON) PROPOSED NEW COUNTIES ONLY
(ALL DATA ON CALENDAR YEAR BASIS)**

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

	Patients	CY 2016 41	CY 2017 42
A. Utilization Data			
B. Revenue from Services to Patients		\$	\$
1. Inpatient Services			
2. Outpatient Services			
3. Emergency Services			
4. Other Operating Revenue (Specify)	See notes page	277,947	284,726
	Gross Operating Revenue	\$ 277,947	\$ 284,726
C. Deductions for Operating Revenue		\$	\$
1. Contractual Adjustments		175,055	179,325
2. Provision for Charity Care		2,779	2,847
3. Provisions for Bad Debt		4,004	4,102
	Total Deductions	\$ 181,838	\$ 186,274
		\$ 96,109	\$ 98,452
NET OPERATING REVENUE			
D. Operating Expenses		\$	
1. Salaries and Wages		45,373	50,672
2. Physicians Salaries and Wages		0	0
3. Supplies		7,411	5,053
4. Taxes		0	0
5. Depreciation		0	0
6. Rent		0	0
7. Interest, other than Capital		0	0
8. Management Fees		0	0
a. Fees to Affiliates		0	0
b. Fees to Non-Affiliates		0	0
9. Other Expenses (Specify)	See notes page	4,807	4,482
	Total Operating Expenses	\$ 57,591	\$ 60,207
E. Other Revenue (Expenses) -- Net (Specify)		\$	\$
		\$ 38,518	\$ 38,245
NET OPERATING INCOME (LOSS)			
F. Capital Expenditures		\$	\$
1. Retirement of Principal			
2. Interest			
	Total Capital Expenditures	\$ 0	\$ 0
NET OPERATING INCOME (LOSS)			
LESS CAPITAL EXPENDITURES			
		\$ 38,518	\$ 38,245

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PROJECTED DATA CHART-- ALERE (DAVIDSON) WITH CURRENT AND PROPOSED COUNTIES
(ALL DATA ON CALENDAR YEAR BASIS)

Give information for the two (2) years following the completion of this proposal.
 The fiscal year begins in January.

	Patients	CY 2016 331	CY 2017 373
A. Utilization Data			
B. Revenue from Services to Patients			
1. Inpatient Services		\$	\$
2. Outpatient Services			
3. Emergency Services			
4. Other Operating Revenue (Specify)			
	See notes page	2,246,623	2,531,348
	Gross Operating Revenue	\$ 2,246,623	\$ 2,531,348
C. Deductions for Operating Revenue			
1. Contractual Adjustments		\$ 1,414,960	\$ 1,594,285
2. Provision for Charity Care		22,466	25,313
3. Provisions for Bad Debt		32,368	36,470
	Total Deductions	\$ 1,469,794	\$ 1,656,068
		\$ 776,829	\$ 875,280
NET OPERATING REVENUE			
D. Operating Expenses			
1. Salaries and Wages		\$ 366,826	\$ 450,498
2. Physicians Salaries and Wages		0	0
3. Supplies		59,903	44,927
4. Taxes		2,890	2,890
5. Depreciation		3,000	2,500
6. Rent		21,600	21,600
7. Interest, other than Capital		0	0
8. Management Fees			
a. Fees to Affiliates		0 0	0
b. Fees to Non-Affiliates		0	0
9. Other Expenses (Specify)	See notes page	50,833	\$ 51,833
	Total Operating Expenses	\$ 505,052	\$ 574,248
E. Other Revenue (Expenses) -- Net (Specify)		\$	\$
NET OPERATING INCOME (LOSS)		\$ 271,777	\$ 301,032
F. Capital Expenditures			
1. Retirement of Principal		\$ 0	\$ 0
2. Interest		0	0
	Total Capital Expenditures	\$ 0	\$ 0
NET OPERATING INCOME (LOSS)			
LESS CAPITAL EXPENDITURES		\$ 271,777	\$ 301,032

Other Expense Detail

	Historical			Projected (Project)		Projected (Expanded Agency)	
	2012	2013	2014	2016	2017	2016	2017
Courier_Postage Exp	20,861	15,854	10,067	972	883	7,853	7,853
Other	3,071	3,310	3,829	247	225	2,000	2,000
Facilities - R&M	1,723	1,192	780			780	780
Facilities - Utilities	1,244	1,169	1,659			1,200	1,200
Telephone	16,221	21,019	21,304			10,000	10,000
Travel	28,448	25,224	26,603	3,464	3,262	28,000	29,000
Misc Sales Expenses	1,323	1,284	1,767	124	112	1,000	1,000
Total Other Exp	72,891	69,052	66,009	4,807	4,482	50,833	51,833

SUPPLEMENTAL

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Thirteen-A : Average Charges, Deductions, and Net Charges Alere/Davidson Agency--Proposed 22 New Counties Only		
	CY2016	CY2017
Patients	42	43
Average Gross Charge Per Patient	\$6,779	\$6,779
Average Deduction Per Patient	\$4,435	\$4,435
Average Net Charge (Net Operating Income) Per Patient	\$2,344	\$2,344
Average Net Operating Income Per Patient After Capital Expenditures	\$939	\$911

Table Thirteen-B : Average Charges, Deductions, and Net Charges Alere / Davidson Agency--Current Plus Proposed Counties		
	CY2016	CY2017
Patients	331	373
Average Gross Charge Per Patient	\$6,787	\$6,786
Average Deduction Per Patient	\$4,440	\$4,440
Average Net Charge (Net Operating Income) Per Patient	\$2,347	\$2,347
Average Net Operating Income Per Patient After Capital Expenditures	\$821	\$807

C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

Table Fourteen: Alere/Davidson's Charges Per Patient		
	CY2014	Year 2--CY2016
Agency Total Unduplicated Patients	200	373
Gross Charges, All Services	\$1,786,408	\$2,531,348
Gross Charges Per Patient	\$8,932	\$6,786

Source: Alere management; Historic and Projected Cost Charts.

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

Table Fifteen-A: Cost & Charge Data of Agencies Currently in the Service Area				
Skilled Nursing				
Agency*	Cost/Visit	Charge/Visit	Cost/Hour	Charge/Hour
1	\$108	\$108	No JAR Data Is Reported For This	NR
2	\$136	\$136		\$40
3	\$106	\$106		\$44
4	\$NR	\$175		\$55
5	\$97	NR		NR
				NR
Alere/Dav'son	NR	NR		

Source: 2014 Joint Annual Reports; and Alere management.

***Key to Agencies:**

1. Elk Valley Home Health Care Agency, LLC (76032)
2. Home health Care of Middle Tennessee, LLC (19584)
3. Quality Home Health (25044)
4. Vanderbilt Community and Home Services (19394)
5. NHC Homecare (75024)

Table Fifteen-B: Alere/Davidson's Average Charges Per Patient (All Counties)		
	Year One--2015	Year Two--2016
Patients	42	43
Total Gross Revenue Per Patient	\$6,787	\$6,786

Source: Maxim management.

The applicant focuses on patients whose youth makes them ineligible for Medicare, so the Medicare fee schedule is not applicable.

C(II).7. DISCUSS HOW PROJECTED UTILIZATION RATES WILL BE SUFFICIENT TO MAINTAIN COST-EFFECTIVENESS.

Because this is a home health service with pre-negotiated reimbursement rates from insurers, and known contractual costs for field personnel and supplies, the expansion proposed in Middle Tennessee will be cost-effective and will operate with a positive margin from the outset.

C(II).8. DISCUSS HOW FINANCIAL VIABILITY WILL BE ENSURED WITHIN TWO YEARS; AND DEMONSTRATE THE AVAILABILITY OF SUFFICIENT CASH FLOW UNTIL FINANCIAL VIABILITY IS MAINTAINED.

This is an existing agency with existing positive cash flow. There will be no delay or interruption in positive cash flow caused by the addition of more patients.

C(II).9. DISCUSS THE PROJECT'S PARTICIPATION IN STATE AND FEDERAL REVENUE PROGRAMS, INCLUDING A DESCRIPTION OF THE EXTENT TO WHICH MEDICARE, TENNCARE/MEDICAID, AND MEDICALLY INDIGENT PATIENTS WILL BE SERVED BY THE PROJECT. IN ADDITION, REPORT THE ESTIMATED DOLLAR AMOUNT OF REVENUE AND PERCENTAGE OF TOTAL PROJECT REVENUE ANTICIPATED FROM EACH OF TENNCARE, MEDICARE, OR OTHER STATE AND FEDERAL SOURCES FOR THE PROPOSAL'S FIRST YEAR OF OPERATION.

Table Sixteen on the following page provides comprehensive payor mix projections for the Alere Davidson County agency.

Table Sixteen: Alere Davidson County Agency--Current and Projected Payor Mix on Gross Revenues (Billings)

	Medicare (All Types)	%	TennCare / Medicaid	%	Commercial	%	Self Pay	%	Other/Charity	%	Total (100%)
2014											
Patients		0.0%	143	71.4%	55	27.6%		0%	2.0	1.0%	200
Gross Revenue		0.0%	\$1,275,495.31	71.4%	\$493,048.61	27.6%		0%	\$17,864.08	1.0%	\$1,786,408.00
Net Revenue		0.0%	\$395,835.13	58.8%	\$270,621.98	40.2%		0%	\$6,731.89	1.0%	\$673,189.00
Gross Revenue/Patient			\$8,919.55		\$8,964.52				\$8,932.04		\$8,932.04
Net Revenue/Patient			\$2,768.08		\$4,920.40				\$3,365.95		\$3,365.95
Year One-2016											
Patients		0.0%	236	71.4%	91	27.6%		0%	4.0	1.0%	331
Gross Revenue		0.0%	\$1,604,088.82	71.4%	\$620,067.95	27.6%		0%	\$22,466.23	1.0%	\$2,246,623.00
Net Revenue		0.0%	\$518,694.64	64.1%	\$282,409.40	34.9%		0%	\$8,091.96	1.0%	\$809,196.00
Gross Revenue/Patient			\$6,796.99		\$6,813.93				\$5,616.56		\$6,787.38
Net Revenue/Patient			\$2,197.86		\$3,103.40				\$2,022.99		\$2,444.70
Year Two-2017											
Patients		0.0%	266	71.4%	103	27.6%		0%	4.0	1.0%	373
Gross Revenue		0.0%	\$1,807,382.47	71.4%	\$698,652.05	27.6%		0%	\$25,313.48	1.0%	\$2,531,348.00
Net Revenue		0.0%	\$584,431.75	64.1%	\$318,200.75	34.9%		0%	\$9,117.50	1.0%	\$911,750.00
Gross Revenue/Patient			\$6,794.67		\$6,783.03				\$6,328.37		\$6,786.46
Net Revenue/Patient			\$2,197.11		\$3,089.33				\$2,279.38		\$2,444.37

Source: Alere management.

Note: This data is on a calendar year basis. It is not consistent with Alere's 2014 Joint Annual Report for two reasons:

1. The JAR is for the period ending June 30, 2014; this table is for the period ending December 31, 2014.
2. Alere has reported net revenue in its JAR rather than gross revenue because Alere bills only on a net revenue basis, at pre-negotiated "bundled" per diem rates. The table above shows gross revenues applicable before negotiating discounts for billing purposes.

C(II).10. PROVIDE COPIES OF THE BALANCE SHEET AND INCOME STATEMENT FROM THE MOST RECENT REPORTING PERIOD OF THE INSTITUTION, AND THE MOST RECENT AUDITED FINANCIAL STATEMENTS WITH ACCOMPANYING NOTES, IF APPLICABLE. FOR NEW PROJECTS, PROVIDE FINANCIAL INFORMATION FOR THE CORPORATION, PARTNERSHIP, OR PRINCIPAL PARTIES INVOLVED WITH THE PROJECT. COPIES MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND LABELED AS ATTACHMENT C, ECONOMIC FEASIBILITY--10.

These are provided as Attachment C, Economic Feasibility--10.

C(II).11. DESCRIBE ALL ALTERNATIVES TO THIS PROJECT WHICH WERE CONSIDERED AND DISCUSS THE ADVANTAGES AND DISADVANTAGES OF EACH ALTERNATIVE, INCLUDING BUT NOT LIMITED TO:

A. A DISCUSSION REGARDING THE AVAILABILITY OF LESS COSTLY, MORE EFFECTIVE, AND/OR MORE EFFICIENT ALTERNATIVE METHODS OF PROVIDING THE BENEFITS INTENDED BY THE PROPOSAL. IF DEVELOPMENT OF SUCH ALTERNATIVES IS NOT PRACTICABLE, THE APPLICANT SHOULD JUSTIFY WHY NOT, INCLUDING REASONS AS TO WHY THEY WERE REJECTED.

B. THE APPLICANT SHOULD DOCUMENT THAT CONSIDERATION HAS BEEN GIVEN TO ALTERNATIVES TO NEW CONSTRUCTION, E.G., MODERNIZATION OR SHARING ARRANGEMENTS. IT SHOULD BE DOCUMENTED THAT SUPERIOR ALTERNATIVES HAVE BEEN IMPLEMENTED TO THE MAXIMUM EXTENT PRACTICABLE.

After the CON process costs are incurred, the only cost to the applicant of implementing the project is a minor expenditure for minor equipment. The entire project cost will not exceed \$84,000, and may cost much less if significant opposition is not encountered during CON review.

The applicant decided to pursue this project due to continuous requests from referring physicians to extend their services into a wider geography. The choice of counties was dictated by a long-range plan to expand Alere into a provider with a wider geographic footprint, for greater ease of contracting with, and serving, the TennCare population that comprises more than 71% of its patients.

C(III).1. LIST ALL EXISTING HEALTH CARE PROVIDERS (I.E., HOSPITALS, NURSING HOMES, HOME CARE ORGANIZATIONS, ETC.) MANAGED CARE ORGANIZATIONS, ALLIANCES, AND/OR NETWORKS WITH WHICH THE APPLICANT CURRENTLY HAS OR PLANS TO HAVE CONTRACTUAL AND/OR WORKING RELATIONSHIPS, E.G., TRANSFER AGREEMENTS, CONTRACTUAL AGREEMENTS FOR HEALTH SERVICES.

Alere does not require transfer agreements because Alere is a service organization rather than a facility. If Alere patients develop a need for hospitalization, their physicians and patients request admission and (if needed) patient transport via ambulance. Alere's most continuous contact is with the three TennCare MCO's who routinely request Alere to provide obstetrical home care to their high-risk enrollees. Alere has negotiated reimbursement contracts with all area MCO's.

C(III).2. DESCRIBE THE POSITIVE AND/OR NEGATIVE EFFECTS OF THE PROPOSAL ON THE HEALTH CARE SYSTEM. PLEASE BE SURE TO DISCUSS ANY INSTANCES OF DUPLICATION OR COMPETITION ARISING FROM YOUR PROPOSAL, INCLUDING A DESCRIPTION OF THE EFFECT THE PROPOSAL WILL HAVE ON THE UTILIZATION RATES OF EXISTING PROVIDERS IN THE SERVICE AREA OF THE PROJECT.

Because the Alere patient base in this area will be so small (43 patients in Year Two) there should be no significant adverse impacts on existing providers--many of whom have few, or no, pregnant women patients.

The project will have positive impacts on patient health in these rural counties. Tennessee is still above the national average for premature births. This rural area and those who pay for its maternal and infant health care needs (particularly TennCare) need to reduce this set of health problems. That will require expansion of clinically sophisticated home care support through proven and financially accessible providers such as Alere. That expansion will create greater awareness and confidence in home care, among referring obstetricians and their patients. The strongest impact of the project will be a positive one that is difficult to quantify--the reduction of costly Emergency Room visits, maternal acute care admissions, NICU admissions of preterm babies, and excessive visits to overcrowded obstetricians' practice offices. These burdensome and expensive events can be significantly reduced by Alere's home care; and it is those patients--rather than other agencies' patient--that Alere's application is targeting.

C(III).3. PROVIDE THE CURRENT AND/OR ANTICIPATED STAFFING PATTERN FOR ALL EMPLOYEES PROVIDING PATIENT CARE FOR THE PROJECT. THIS CAN BE REPORTED USING FTE'S FOR THESE POSITIONS. IN ADDITION, PLEASE COMPARE THE CLINICAL STAFF SALARIES IN THE PROPOSAL TO PREVAILING WAGE PATTERNS IN THE SERVICE AREA AS PUBLISHED BY THE TENNESSEE DEPARTMENT OF LABOR & WORKFORCE DEVELOPMENT AND/OR OTHER DOCUMENTED SOURCES.

The Department of Labor and Workforce Development website indicates the following Middle Tennessee region's annual salary information for clinical employees of this project:

Table Seventeen: TDOL Surveyed Average Salaries for the Region				
Position	Entry Level	Mean	Median	Experienced
RN annual	\$42,404	\$55,866	\$55,637	\$62,597
RN Hourly	\$20.40	\$26.85	\$26.75	\$30.10

Please see the following page for Table Eighteen, which shows the project's FTE's and salary ranges.

**Table Eighteen: Alere / Davidson County Agency
Current and Projected Staffing**

Position Type (RN, etc.)	Current 2015 FTE's	Yr 1 2016 FTE's	Yr 2 2017 FTE's	Annual Salary Range 2015	
				Minimum	Maximum
Office Positions, Management and Clinical					
Administrative Assistant (Nashville)	1.0	1.00	1.00	\$27,892.00	\$48,900.00
Home Care Director (Nashville)	1.0	1.00	1.00	\$57,800.00	\$103,700.00
Administrative Assistant (Call Center Support)	1	1.22	1.50	\$27,892.00	\$48,900.00
Perinatal Clinicians (Call Center Support)	1	1.14	1.30	\$40,810.00	\$72,300.00
Account Executive	0.33	0.33	0.33	\$45,500.00	\$80,100.00
Subtotal, Office FTE's	4.33	4.69	5.13		
Clinical Positions in Field (Direct Patient Care)					
Patient Educators Current = 10 RNs 2015 = 17 RNs 2016 = 24 RNs	3	5.00	7.00	\$48,505.00	\$86,403.00
Subtotal, Field FTE's	3	5.00	7.00		
Total, Office and Field FTE's	7.33	9.69	12.13		

Source: Alere Management

C(III).4. DISCUSS THE AVAILABILITY OF AND ACCESSIBILITY TO HUMAN RESOURCES REQUIRED BY THE PROPOSAL, INCLUDING ADEQUATE PROFESSIONAL STAFF, AS PER THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, AND/OR THE DIVISION OF MENTAL RETARDATION SERVICES LICENSING REQUIREMENTS.

Currently Alere/Davidson's pool consists of 10 OB RN's. Some of these live in close proximity to one or more of the proposed counties, so Alere can begin service to those counties immediately after CON approval.

The addition of all 22 new counties with their estimated 42-43 additional patients, combined with the anticipated growth of cases within Alere/Davidson's current service area, will cause Alere's OB RN employees to increase from 10 RNs to 24 RNs by CY2017. Days of service requested of these 14 additional RN's (and their central office and call center support staff) will cumulatively total approximately 4.8 FTE equivalents, as indicated by the staffing data in Table Eighteen. Of that, 4.0 FTE equivalents are cumulative per diems from the pool of qualified OB RN's who are employed by Alere to perform home care services under Alere protocols and the direction of supervising physicians.

C(III).5. VERIFY THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSING CERTIFICATION AS REQUIRED BY THE STATE OF TENNESSEE FOR MEDICAL/CLINICAL STAFF. THESE INCLUDE, WITHOUT LIMITATION, REGULATIONS CONCERNING PHYSICIAN SUPERVISION, CREDENTIALING, ADMISSIONS PRIVILEGES, QUALITY ASSURANCE POLICIES AND PROGRAMS, UTILIZATION REVIEW PPOLICIES AND PROGRAMS, RECORD KEEPING, AND STAFF EDUCATION.

The applicant so verifies.

C(III).6. DISCUSS YOUR HEALTH CARE INSTITUTION'S PARTICIPATION IN THE TRAINING OF STUDENTS IN THE AREAS OF MEDICINE, NURSING, SOCIAL WORK, ETC. (I.E., INTERNSHIPS, RESIDENCIES, ETC.).

This agency does not participate in the training of health care professionals.

C(III).7(a). PLEASE VERIFY, AS APPLICABLE, THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSURE REQUIREMENTS OF THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, THE DIVISION OF MENTAL RETARDATION SERVICES, AND/OR ANY APPLICABLE MEDICARE REQUIREMENTS.

The applicant so verifies.

C(III).7(b). PROVIDE THE NAME OF THE ENTITY FROM WHICH THE APPLICANT HAS RECEIVED OR WILL RECEIVE LICENSURE, CERTIFICATION, AND/OR ACCREDITATION

LICENSURE: Board for Licensure of Healthcare Facilities
Tennessee Department of Health

CERTIFICATION: TennCare Certification from TDH

ACCREDITATION: Joint Commission (System-wide)

C(III).7(c). IF AN EXISTING INSTITUTION, PLEASE DESCRIBE THE CURRENT STANDING WITH ANY LICENSING, CERTIFYING, OR ACCREDITING AGENCY OR AGENCY.

The applicant is currently licensed in good standing by the Board for Licensing Health Care Facilities, certified for participation in Medicaid/TennCare, and fully "system-wide" accredited by the Joint Commission (JC). System-wide accreditation is the JC's process for efficient accreditation of a large system of agencies by surveys of a random sampling of their sites. This suffices to provide a "system-wide" accreditation of all the providers' sites. Alere has earned the Joint Commission's Gold Seal for system-wide excellence.

None of Alere's Tennessee agencies has been selected as a JC system-wide survey site. Please see the relevant documents in the Attachments for the survey results of JC's selected sites. The JC accreditation letter is addressed to the Alere office responsible for all Alere accreditation activities.

C(III).7(d). FOR EXISTING LICENSED PROVIDERS, DOCUMENT THAT ALL DEFICIENCIES (IF ANY) CITED IN THE LAST LICENSURE CERTIFICATION AND INSPECTION HAVE BEEN ADDRESSED THROUGH AN APPROVED PLAN OF CORRECTION. PLEASE INCLUDE A COPY OF THE MOST RECENT LICENSURE/CERTIFICATION INSPECTION WITH AN APPROVED PLAN OF CORRECTION.

They have been addressed. A copy of the most recent licensure inspection and plan of correction, and/or the most recent accreditation inspection, are provided in Attachment C, Orderly Development--7(C).

C(III)8. DOCUMENT AND EXPLAIN ANY FINAL ORDERS OR JUDGMENTS ENTERED IN ANY STATE OR COUNTRY BY A LICENSING AGENCY OR COURT AGAINST PROFESSIONAL LICENSES HELD BY THE APPLICANT OR ANY ENTITIES OR PERSONS WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE APPLICANT. SUCH INFORMATION IS TO BE PROVIDED FOR LICENSES REGARDLESS OF WHETHER SUCH LICENSE IS CURRENTLY HELD.

None.

C(III)9. IDENTIFY AND EXPLAIN ANY FINAL CIVIL OR CRIMINAL JUDGMENTS FOR FRAUD OR THEFT AGAINST ANY PERSON OR ENTITY WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE PROJECT.

None.

C(III)10. IF THE PROPOSAL IS APPROVED, PLEASE DISCUSS WHETHER THE APPLICANT WILL PROVIDE THE THSDA AND/OR THE REVIEWING AGENCY INFORMATION CONCERNING THE NUMBER OF PATIENTS TREATED, THE NUMBER AND TYPE OF PROCEDURES PERFORMED, AND OTHER DATA AS REQUIRED.

Yes. The applicant will provide the requested data consistent with Federal HIPAA requirements.

PROOF OF PUBLICATION

Attached.

DEVELOPMENT SCHEDULE

1. PLEASE COMPLETE THE PROJECT COMPLETION FORECAST CHART ON THE NEXT PAGE. IF THE PROJECT WILL BE COMPLETED IN MULTIPLE PHASES, PLEASE IDENTIFY THE ANTICIPATED COMPLETION DATE FOR EACH PHASE.

The Project Completion Forecast Chart is provided after this page.

2. IF THE RESPONSE TO THE PRECEDING QUESTION INDICATES THAT THE APPLICANT DOES NOT ANTICIPATE COMPLETING THE PROJECT WITHIN THE PERIOD OF VALIDITY AS DEFINED IN THE PRECEDING PARAGRAPH, PLEASE STATE BELOW ANY REQUEST FOR AN EXTENDED SCHEDULE AND DOCUMENT THE "GOOD CAUSE" FOR SUCH AN EXTENSION.

Not applicable. The applicant anticipates completing the project within the period of validity.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision Date, as published in Rule 68-11-1609(c):

September 23, 2015

Assuming the CON decision becomes the final Agency action on that date, indicate the number of days from the above agency decision date to each phase of the completion forecast.

PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Architectural & engineering contract signed		
2. Construction documents approved by TDH		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete		
10. * Issuance of license	NA	NA
11. *Initiation of service	7	10-1-15
12. Final architectural certification of payment	NA	NA
13. Final Project Report Form (HF0055)	9	12-15

*** For projects that do NOT involve construction or renovation: please complete items 10-11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

AFFIDAVITSTATE OF TENNESSEECOUNTY OF DAVIDSON

JOHN WELLBORN, being first duly sworn, says that he is the lawful agent of the applicant named in this application, that this project will be completed in accordance with the application to the best of the agent's knowledge, that the agent has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete to the best of the agent's knowledge.



John Wellborn
SIGNATURE/TITLE
CONSULTANT

Sworn to and subscribed before me this 12th day of June, 2015 a Notary
(Month) (Year)

Public in and for the County/State of DAVIDSON

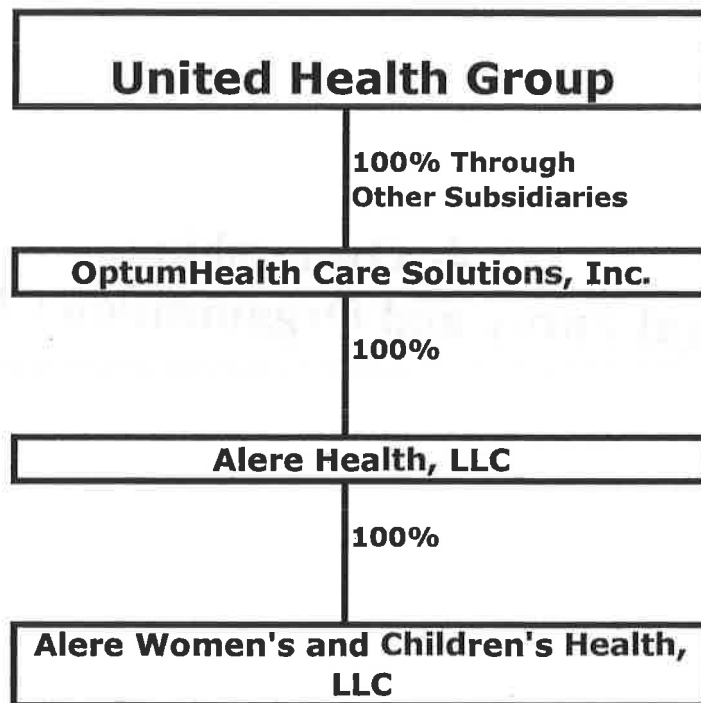
[Signature]
NOTARY PUBLIC

My commission expires July 2, 2018.
(Month/Day) (Year)

INDEX OF ATTACHMENTS

A.4	Ownership--Legal Entity Documentation
C, Need--3	Service Area Maps
C, Economic Feasibility--2	Documentation of Availability of Funding
C, Economic Feasibility--10	Financial Statements
C, Orderly Development--7(C)	Licensing & Accreditation Inspections
Miscellaneous Information	1. Base Table 1 (Existing Agency Statistics) 2. Tables Seven-C and Seven-D 3. TennCare Enrollments By County, 4-15-15
Support Letters	

**A.4--Ownership
Legal Entity and Organization Chart**



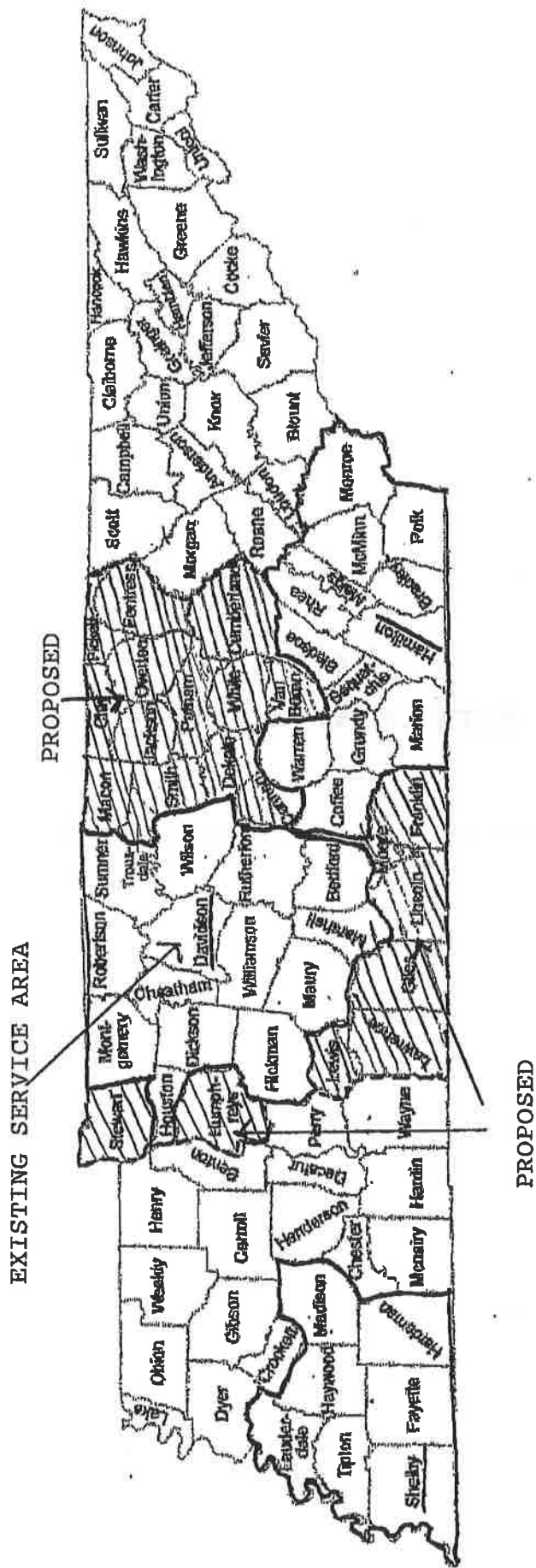
Alere Women's and Children's Health, LLC Licensed Home Care Agencies in Tennessee	
Home Care Agency	Licensed Counties
SOUTHEAST TENNESSEE Alere Women's and Children's Health, LLC 651 East Fourth Street, Suite 100 Chattanooga, TN 37403 Angela Coffee, RN 423-634-3207	Bledsoe
	Bradley
	Coffee
	Grundy
	Hamilton
	Marion
	McMinn
	Meigs
	Monroe
	Polk
	Rhea
	Sequatchie
	Warren
	(13 counties)
WEST TENNESSEE Alere Women's and Children's Health, LLC 7519 Capital Drive, Suite 2 Germantown, TN 38138 Elizabeth Summers (901)756-6444	Fayette
	Hardeman
	Haywood
	Lauderdale
	Madison
	Shelby
	Tipton
	(7 counties)
MIDDLE TENNESSEE Alere Women's and Children's Health, LLC 1926 Hayes Street, Suite 111 Nashville, TN 37203 Laura Milner, RN 615-320-3270	Bedford
	Cheatham
	Davidson
	Dickson
	Hickman
	Houston
	Marshall
	Maury
	Montgomery
	Robertson
	Rutherford
	Sumner
	Williamson
	Wilson
	(14 counties)

Notes on Alere Women's and Children's Health, LLC

The applicant is Alere Women's and Children's Health, LLC. Its present name is the result of several reorganizations and name changes that are summarized below. The first page of this Attachment is documentation from the Tennessee Secretary of State that it is registered in good standing to do business in Tennessee.

Some years ago, two corporations named Tokos and Healthdyne merged, with Healthdyne being the surviving corporation, which then changed its name to Matria Healthcare, Inc. and then changed it again to Matria Women's and Children's Health, Inc. By special authorization of the IRS, it was allowed to convert into an LLC, Matria Women's and Children's Health, LLC. That LLC changed its name to Alere Women's and Children's Health, LLC, the applicant's current name. From Healthdyne on, this entity has kept the same tax ID number and has been the same legal entity for purposes of a Certificate of Need application.

C, Need--3
Service Area Maps



C, Economic Feasibility--2
Documentation of Availability of Funding

**June 25, 2015****3:30 pm** 13625 Technology Drive
Eden Prairie, MN 55344

www.optum.com

June 17, 2015

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson State Office Building, 9th Floor
500 Deaderick Street
Nashville, Tennessee 37243

RE: CON Application to Add Service Area Counties
Alere Women's and Children's Health, LLC – Davidson County

Dear Mrs. Hill:

Alere Women's and Children's Health, LLC has filed a Certificate of Need Application to expand the service area of its Davidson County home healthcare agency. The estimated cost to implement the project is \$84,000.

Alere Women's and Children's Health, LLC is wholly owned by Alere Health, LLC, which is wholly owned by OptumHealth Care Solutions, Inc. (part of OptumHealth), which is ultimately wholly owned by UnitedHealth Group, a publicly traded company.

I am writing to confirm that the project's cost will be funded entirely by a cash transfer to the applicant through the organizational chain described above. As Chief Financial Officer of OptumHealth Care Solutions, Inc., I am authorized to make that commitment. The availability of sufficient cash is shown in financial statements in the attached UnitedHealth Group's Security and Exchange Commission filings on Form 10-K for the year ended December 31, 2014 and Form 10-Q for the quarter ended March 31, 2015.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joel Costa'.

Joel Costa
Chief Financial Officer
OptumHealth Care Solutions, Inc.

C, Economic Feasibility--10
Financial Statements

UnitedHealth Group
Consolidated Balance Sheets

(in millions, except per share data)	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,495	\$ 7,276
Short-term investments	1,741	1,937
Accounts receivable, net of allowances of \$260 and \$196	4,252	3,052
Other current receivables, net of allowances of \$156 and \$169	5,498	3,998
Assets under management	2,962	2,757
Deferred income taxes	556	430
Prepaid expenses and other current assets	1,052	930
Total current assets	23,556	20,380
Long-term investments	18,827	19,605
Property, equipment and capitalized software, net of accumulated depreciation and amortization of \$2,954 and \$2,675	4,418	4,010
Goodwill	32,940	31,604
Other intangible assets, net of accumulated amortization of \$2,685 and \$2,283	3,669	3,844
Other assets	2,972	2,439
Total assets	\$86,382	\$81,882
Liabilities and shareholders' equity		
Current liabilities:		
Medical costs payable	\$12,040	\$11,575
Accounts payable and accrued liabilities	9,247	7,458
Other policy liabilities	5,965	5,279
Commercial paper and current maturities of long-term debt	1,399	1,969
Unearned revenues	1,972	1,600
Total current liabilities	30,623	27,881
Long-term debt, less current maturities	16,007	14,891
Future policy benefits	2,488	2,465
Deferred income taxes	2,065	1,796
Other liabilities	1,357	1,525
Total liabilities	52,540	48,558
Commitments and contingencies (Note 12)		
Redeemable noncontrolling interests	1,388	1,175
Shareholders' equity:		
Preferred stock, \$0.001 par value — 10 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.01 par value — 3,000 shares authorized; 954 and 988 issued and outstanding	10	10
Retained earnings	33,836	33,047
Accumulated other comprehensive loss	(1,392)	(908)
Total shareholders' equity	32,454	32,149
Total liabilities and shareholders' equity	\$86,382	\$81,882

See Notes to the Consolidated Financial Statements

UnitedHealth Group
Consolidated Statements of Operations

	For the Years Ended December 31,		
	2014	2013	2012
(in millions, except per share data)			
Revenues:			
Premiums	\$115,302	\$109,557	\$ 99,728
Services	10,151	8,997	7,437
Products	4,242	3,190	2,773
Investment and other income	779	745	680
Total revenues	130,474	122,489	110,618
Operating costs:			
Medical costs	93,257	89,290	80,226
Operating costs	21,681	19,362	17,306
Cost of products sold	3,784	2,839	2,523
Depreciation and amortization	1,478	1,375	1,309
Total operating costs	120,200	112,866	101,364
Earnings from operations	10,274	9,623	9,254
Interest expense	(618)	(708)	(632)
Earnings before income taxes	9,656	8,915	8,622
Provision for income taxes	(4,037)	(3,242)	(3,096)
Net earnings	5,619	5,673	5,526
Earnings attributable to noncontrolling interests	—	(48)	—
Net earnings attributable to UnitedHealth Group common shareholders	\$ 5,619	\$ 5,625	\$ 5,526
Earnings per share attributable to UnitedHealth Group common shareholders:			
Basic	\$ 5.78	\$ 5.59	\$ 5.38
Diluted	\$ 5.70	\$ 5.50	\$ 5.28
Basic weighted-average number of common shares outstanding	972	1,006	1,027
Dilutive effect of common share equivalents	14	17	19
Diluted weighted-average number of common shares outstanding	986	1,023	1,046
Anti-dilutive shares excluded from the calculation of dilutive effect of common share equivalents	6	8	17
Cash dividends declared per common share	\$ 1.4050	\$ 1.0525	\$ 0.8000

See Notes to the Consolidated Financial Statements

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2015

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 1-10864

UNITEDHEALTH GROUP®

UnitedHealth Group Incorporated

(Exact name of registrant as specified in its charter)

Minnesota
(State or other jurisdiction of
incorporation or organization)

41-1321939
(I.R.S. Employer
Identification No.)

UnitedHealth Group Center
9900 Bren Road East
Minnetonka, Minnesota
(Address of principal executive offices)

55343
(Zip Code)

(952) 936-1300

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 30, 2015, there were 951,904,261 shares of the registrant's Common Stock, \$.01 par value per share, issued and outstanding.



UNITEDHEALTH GROUP

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PART I

ITEM 1. FINANCIAL STATEMENTS

UnitedHealth Group
Condensed Consolidated Balance Sheets
(Unaudited)

(in millions, except per share data)	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,650	\$ 7,495
Short-term investments	1,780	1,741
Accounts receivable, net	5,040	4,252
Other current receivables, net	5,346	5,498
Assets under management	2,921	2,962
Deferred income taxes	405	556
Prepaid expenses and other current assets	2,632	1,052
Total current assets	26,774	23,556
Long-term investments	19,416	18,827
Property, equipment and capitalized software, net	4,245	4,418
Goodwill	32,782	32,940
Other intangible assets, net	3,441	3,669
Other assets	3,061	2,972
Total assets	<u>\$89,719</u>	<u>\$86,382</u>
Liabilities and shareholders' equity		
Current liabilities:		
Medical costs payable	\$13,537	\$12,040
Accounts payable and accrued liabilities	10,518	9,247
Other policy liabilities	6,392	5,965
Commercial paper and current maturities of long-term debt	2,797	1,399
Unearned revenues	1,734	1,972
Total current liabilities	34,978	30,623
Long-term debt, less current maturities	15,577	16,007
Future policy benefits	2,483	2,488
Deferred income taxes	2,056	2,065
Other liabilities	1,295	1,357
Total liabilities	<u>56,389</u>	<u>52,540</u>
Commitments and contingencies (Note 9)		
Redeemable noncontrolling interests	1,452	1,388
Shareholders' equity:		
Preferred stock, \$0.001 par value — 10 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.01 par value — 3,000 shares authorized; 952 and 954 issued and outstanding	10	10
Retained earnings	34,153	33,836
Accumulated other comprehensive loss	(2,285)	(1,392)
Total shareholders' equity	<u>31,878</u>	<u>32,454</u>
Total liabilities and shareholders' equity	<u>\$89,719</u>	<u>\$86,382</u>

See Notes to the Condensed Consolidated Financial Statements

UnitedHealth Group
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2015	2014
(in millions, except per share data)		
Revenues:	\$31,674	\$28,115
Premiums	2,706	2,404
Services	1,230	998
Products	146	191
Investment and other income	35,756	31,708
Total revenues		
Operating costs:	25,689	23,208
Medical costs	5,949	5,194
Operating costs	1,100	892
Cost of products sold	378	360
Depreciation and amortization	33,116	29,654
Total operating costs	2,640	2,054
Earnings from operations	(150)	(160)
Interest expense	2,490	1,894
Earnings before income taxes	(1,077)	(795)
Provision for income taxes	\$ 1,413	\$ 1,099
Net earnings		
Earnings per share:	\$ 1.48	\$ 1.12
Basic	\$ 1.46	\$ 1.10
Diluted	954	983
Basic weighted-average number of common shares outstanding	15	13
Dilutive effect of common share equivalents	969	996
Diluted weighted-average number of common shares outstanding		
Anti-dilutive shares excluded from the calculation of dilutive effect of common share equivalents	9	9
Cash dividends declared per common share	\$0.3750	\$0.2800

See Notes to the Condensed Consolidated Financial Statements

UnitedHealth Group
Condensed Consolidated Statements of Comprehensive Income
(Unaudited)

(in millions)	Three Months Ended March 31,	
	2015	2014
Net earnings	\$ 1,413	\$ 1,099
Other comprehensive (loss) income:		
Gross unrealized gains on investment securities during the period	105	166
Income tax effect	(37)	(61)
Total unrealized gains, net of tax	68	105
Gross reclassification adjustment for net realized gains included in net earnings	(3)	(46)
Income tax effect	1	17
Total reclassification adjustment, net of tax	(2)	(29)
Total foreign currency translation (losses) gains	(959)	259
Other comprehensive (loss) income	(893)	335
Comprehensive income	\$ 520	\$ 1,434

See Notes to the Condensed Consolidated Financial Statements



10. Segment Financial Information

The Company's four reportable segments are UnitedHealthcare, OptumHealth, OptumInsight and OptumRx. For more information on the Company's segments see Part I, Item I, "Business" and Note 13 of Notes to the Consolidated Financial Statements in Part II, Item 8, "Financial Statements" in the Company's 2014 10-K.

The following table presents the reportable segment financial information:

	Optum						Corporate and Eliminations	Consolidated
(in millions)	UnitedHealthcare	OptumHealth	OptumInsight	OptumRx	Optum Eliminations	Optum		
Three Months Ended March 31, 2015								
Revenues — external customers:								
Premiums	\$ 30,905	\$ 769	\$ —	\$ —	\$ —	\$ 769	\$ —	\$ 31,674
Services	1,603	521	559	23	—	1,103	—	2,706
Products	—	5	20	1,205	—	1,230	—	1,230
Total revenues — external customers	32,508	1,295	579	1,228	—	3,102	—	35,610
Total revenues — intersegment	—	1,963	811	7,067	(159)	9,682	(9,682)	—
Investment and other income	115	31	—	—	—	31	—	146
Total revenues	\$ 32,623	\$ 3,289	\$ 1,390	\$ 8,295	\$ (159)	\$ 12,815	\$ (9,682)	\$ 35,756
Earnings from operations	\$ 1,898	\$ 234	\$ 222	\$ 286	\$ —	\$ 742	\$ —	\$ 2,640
Interest expense	—	—	—	—	—	—	(150)	(150)
Earnings before income taxes	\$ 1,898	\$ 234	\$ 222	\$ 286	\$ —	\$ 742	\$ (150)	\$ 2,490
Three Months Ended March 31, 2014								
Revenues — external customers:								
Premiums	\$ 27,511	\$ 604	\$ —	\$ —	\$ —	\$ 604	\$ —	\$ 28,115
Services	1,586	263	525	30	—	818	—	2,404
Products	1	7	26	964	—	997	—	998
Total revenues — external customers	29,098	874	551	994	—	2,419	—	31,517
Total revenues — intersegment	—	1,671	696	6,464	(115)	8,716	(8,716)	—
Investment and other income	156	35	—	—	—	35	—	191
Total revenues	\$ 29,254	\$ 2,580	\$ 1,247	\$ 7,458	\$ (115)	\$ 11,170	\$ (8,716)	\$ 31,708
Earnings from operations	\$ 1,404	\$ 211	\$ 197	\$ 242	\$ —	\$ 650	\$ —	\$ 2,054
Interest expense	—	—	—	—	—	—	(160)	(160)
Earnings before income taxes	\$ 1,404	\$ 211	\$ 197	\$ 242	\$ —	\$ 650	\$ (160)	\$ 1,894

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

June 25, 2015

3:30 pm

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 1-10864

UNITEDHEALTH GROUP®

UnitedHealth Group Incorporated

(Exact name of registrant as specified in its charter)

Minnesota
(State or other jurisdiction of
incorporation or organization)

41-1321939
(I.R.S. Employer
Identification No.)

UnitedHealth Group Center
9900 Bren Road East
Minnetonka, Minnesota
(Address of principal executive offices)

55343
(Zip Code)

(952) 936-1300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, \$.01 PAR VALUE
(Title of each class)

NEW YORK STOCK EXCHANGE, INC.
(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer ☒
Non-accelerated filer ☐

Accelerated filer ☐
Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2014 was \$78,282,268,950 (based on the last reported sale price of \$81.75 per share on June 30, 2014, on the New York Stock Exchange), excluding only shares of voting stock held beneficially by directors, executive officers and subsidiaries of the registrant.

As of January 30, 2015, there were 953,695,161 shares of the registrant's Common Stock, \$.01 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to its 2015 Annual Meeting of Stockholders. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

PART I**ITEM 1. BUSINESS****INTRODUCTION****Overview**

UnitedHealth Group is a diversified health and well-being company dedicated to helping people live healthier lives and making the health system work better for everyone. The terms “we,” “our,” “us,” “its,” “UnitedHealth Group,” or the “Company” used in this report refer to UnitedHealth Group Incorporated and its subsidiaries.

Through our diversified family of businesses, we leverage core competencies in advanced, enabling technology; health care data, information and intelligence; and clinical care management and coordination to help meet the demands of the health system. These core competencies are deployed within our two distinct, but strategically aligned, business platforms: health benefits operating under UnitedHealthcare and health services operating under Optum.

UnitedHealthcare provides health care benefits to an array of customers and markets. UnitedHealthcare Employer & Individual serves employers ranging from sole proprietorships to large, multi-site and national employers, public sector employers, students and other individuals and serves the nation’s active and retired military and their families through the TRICARE program. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits for Medicare beneficiaries and retirees. UnitedHealthcare Community & State manages health care benefit programs on behalf of state Medicaid and community programs and their participants. UnitedHealthcare Global (formerly UnitedHealthcare International) includes Amil, a health care company providing health and dental benefits and hospital and clinical services to individuals in Brazil, and other diversified global health businesses.

Optum is a health services business serving the broad health care marketplace, including payers, care providers, employers, governments, life sciences companies and consumers, through its OptumHealth, OptumInsight and OptumRx businesses. These businesses have dedicated units that help improve overall health system performance through optimizing care quality, reducing costs and improving consumer experience and care provider performance across eight business markets: local care delivery, care management, consumer engagement, distribution services, health financial services, operational services and support, health care information technology and pharmacy services.

Through UnitedHealthcare and Optum, in 2014, we managed over \$165 billion in aggregate health care spending on behalf of the customers and consumers we serve. Our revenues are derived from premiums on risk-based products; fees from management, administrative, technology and consulting services; sales of a wide variety of products and services related to the broad health and well-being industry; and investment and other income. Our two business platforms have four reportable segments:

- UnitedHealthcare, which includes UnitedHealthcare Employer & Individual, UnitedHealthcare Medicare & Retirement, UnitedHealthcare Community & State and UnitedHealthcare Global;
- OptumHealth;
- OptumInsight; and
- OptumRx.

For our financial results and the presentation of certain other financial information by segment, including revenues and long-lived fixed assets by geographic source, see Note 13 of Notes to the Consolidated Financial Statements included in Part II, Item 8, “Financial Statements.”

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UnitedHealthcare's market position is built on:

- national scale;
- strong local market relationships;
- the breadth of product offerings, which are responsive to many distinct market segments in health care;
- service and advanced technology;
- competitive medical and operating cost positions;
- effective clinical engagement;
- extensive expertise in distinct market segments; and
- innovation for customers and consumers.

UnitedHealthcare utilizes the expertise of UnitedHealth Group affiliates for capabilities in specialized areas, such as OptumRx pharmacy benefit products and services, certain OptumHealth care management and local care delivery services and OptumInsight health information and technology solutions, consulting and other services.

In the United States, UnitedHealthcare arranges for discounted access to care through networks that include a total of over 850,000 physicians and other health care professionals and approximately 6,100 hospitals and other facilities.

UnitedHealthcare is subject to extensive government regulation. See further discussion of our regulatory environment below under "Government Regulation" and in Part II, Item 7, "Management Discussion and Analysis of Financial Condition and Results of Operations."

UnitedHealthcare Employer & Individual

UnitedHealthcare Employer & Individual offers an array of consumer-oriented health benefit plans and services for large national employers, public sector employers, mid-sized employers, small businesses, individuals and military service members in the TRICARE west region. UnitedHealthcare Employer & Individual provides nearly 29 million Americans access to health care as of December 31, 2014. Large employer groups typically use self-funded arrangements where UnitedHealthcare Employer & Individual earns a service fee. Smaller employer groups and individuals are more likely to purchase risk-based products because they are less willing or unable to bear a greater potential liability for health care expenditures.

Through its risk-based product offerings, UnitedHealthcare Employer & Individual assumes the risk of both medical and administrative costs for its customers in return for a monthly premium, which is typically a fixed rate per individual served for a one-year period. When providing administrative and other management services to customers that elect to self-fund the health care costs of their employees and employees' dependents, UnitedHealthcare Employer & Individual receives a fixed monthly service fee per individual served. These customers retain the risk of financing medical benefits for their employees and employees' dependents, while UnitedHealthcare Employer & Individual provides services such as coordination and facilitation of medical and related services to customers, consumers and health care professionals, administration of transaction processing and access to a contracted network of physicians, hospitals and other health care professionals, including dental and vision.

UnitedHealthcare Employer & Individual also offers a variety of insurance options for purchase by individuals, including students, which are designed to meet the health coverage needs of these consumers and their families. The consolidated purchasing capacity represented by the individuals UnitedHealth Group serves makes it possible for UnitedHealthcare Employer & Individual to contract for cost-effective access to a large number of conveniently located care professionals and facilities.

June 25, 2015**3:30 pm**

UnitedHealthcare Employer & Individual typically distributes its products through consultants or direct sales in the larger employer and public sector segments. In the smaller group segment of the commercial marketplace, UnitedHealthcare Employer & Individual's distribution system consists primarily of direct sales and sales through collaboration with brokers and agents. UnitedHealthcare Employer & Individual also distributes products through wholesale agents or agencies that contract with health insurance carriers to distribute individual or group benefits and provide other related services to their customers.

In recent years, UnitedHealthcare Employer & Individual has diversified its model more extensively, distributing through professional employer organizations, associations, private equity relationships and, increasingly, through both multi-carrier and its own proprietary private exchange marketplaces. In 2014, UnitedHealthcare Employer & Individual launched UnitedHealthcare Marketplace, a new shopping platform for employers seeking to offer their employees flexibility and a choice of UnitedHealthcare plans. UnitedHealthcare Employer & Individual is also participating in select multi-plan exchanges that they believe are structured to encourage consumer choice. Direct-to-consumer sales are also supported by participation in multi-carrier health insurance marketplaces for individuals and small groups through exchanges. In 2014, UnitedHealthcare Employer & Individual participated in 13 state public health care exchanges, including four individual and nine small group exchanges. In 2015, we are participating in 23 individual and 12 small group state public exchanges.

UnitedHealthcare Employer & Individual's diverse product portfolio offers a continuum of benefit designs, price points and approaches to consumer engagement, which provide the flexibility to meet the needs of employers of all sizes, as well as individuals shopping for health benefits coverage. UnitedHealthcare Employer & Individual has seen increased demand for consumer driven health plans and new network approaches with lower costs, as well as more convenient care options for consumers. UnitedHealthcare Employer & Individual emphasizes local markets and leverages its national scale to adapt products to meet specific local market needs.

UnitedHealthcare Employer & Individual offers its products through affiliates that are licensed as insurance companies, health maintenance organizations (HMOs), or third-party administrators (TPAs). The market for health benefit products is shifting, with benefit and network offerings shaped, at least in part, by the requirements and effects of the Patient Protection and Affordable Care Act and a reconciliation measure, the Health Care and Education Reconciliation Act of 2010 (together, Health Reform Legislation), employer focus on quality and employee engagement, and the urgent need to align the system around value.

UnitedHealthcare Employer & Individual's major product families include:

Traditional Products. Traditional products include a full range of medical benefits and network options from managed plans, such as Choice and Options PPO, to more traditional indemnity products. The plans offer a full spectrum of covered services, including preventive care, direct access to specialists and catastrophic protection.

Consumer Engagement Products and Tools. Consumer engagement products couple plan design with financial accounts to increase individuals' responsibility for their health and well-being. This suite of products includes high-deductible consumer-driven benefit plans, which include health reimbursement accounts (HRAs), health savings accounts (HSAs) and consumer engagement services such as personalized behavioral incentive programs and consumer education. During 2014, more than 32,000 employer-sponsored benefit plans, including more than 300 employers in the large group self-funded market, purchased HRA or HSA products from us. UnitedHealthcare Employer & Individual's consumer engagement tools support members with access to benefit, cost and quality information through online and mobile applications, such as Advocate4Me, myHealthcare Cost Estimator and Health4Me. Using innovative tools and technology, UnitedHealthcare and Optum's applications are helping people address a broad range of health related issues, including benefits and claims questions, finding the right doctor, proactive support for appointments and issue resolution, health education, clinical program enrollment and treatment decision support.

Value Based Products. UnitedHealthcare Employer & Individual's suite of consumer incentive products increases individual awareness of personal health and care quality and cost for heightened consumer responsibility and behavior change. These products include: Small Business Wellness, which is a packaged

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wellness and incentives product that offers gym reimbursement and encourages completion of important wellness activities. For mid-sized clients, SimplyEngaged is a scalable activity-based reward program that ties incentives to completion of health improvement activities, while SimplyEngaged Plus provides richer incentives for achieving health goals. For large, self-funded customers, the UnitedHealthcare Healthy Rewards program offers a flexible incentive design to help employers choose the right activities and include appropriate biometric outcomes that best fit the needs of their employee population. UnitedHealth Personal Rewards leverages a tailored approach to incentives by combining personalized scorecards with financial incentives for improving biometric scores, compliance with key health treatments and preventive care.

Essential Benefits Products. UnitedHealthcare Employer & Individual's portfolio of lower cost products provides value to consumers through innovative plan designs and unique network programs like UnitedHealth Premium®, which guide people to physicians recognized for providing high-quality, cost-efficient care to their patients. This approach to essential benefits is designed to deliver sustainable health care costs for employers, enabling them to continue to offer their employees coverage at more affordable prices. For example, UnitedHealthcare Employer & Individual's tiered benefit plans offer enhanced benefits in the form of greater coinsurance coverage and/or lower copays for people using UnitedHealth Premium® designated care providers.

Clinical and Pharmacy Products. UnitedHealthcare Employer & Individual offers a comprehensive suite of clinical and pharmacy benefits management programs, which complement its service offerings by improving quality of care, engaging members and providing cost-saving options. All UnitedHealthcare Employer & Individual members are provided access to clinical products that help them make better health care decisions and better use of their medical benefits, improving health and decreasing medical expenses.

Each medical plan has a core set of clinical programs embedded in the offering, with additional services available depending on funding type (fully insured or self-funded), line of business (e.g., small business, key accounts, public sector, national accounts and individuals), and clinical need. UnitedHealthcare Employer & Individual's clinical programs include:

- wellness programs;
- decision support;
- utilization management;
- case and disease management;
- complex condition management;
- on-site programs, including Know Your Numbers (biometrics) and flu shots;
- incentives to reinforce positive behavior change;
- mental health/substance use disorder management; and
- employee assistance programs.

UnitedHealthcare Employer & Individual's comprehensive and integrated pharmaceutical management services promote lower costs by using formulary programs to produce better unit costs, encouraging consumers to use drugs that offer improved value and outcomes, and supporting the appropriate use of drugs based on clinical evidence through physician and consumer education programs.

Specialty Offerings. UnitedHealthcare Employer & Individual also delivers dental, vision, life, and disability product offerings through an integrated approach including a network of more than 58,000 vision professionals in private and retail settings, and nearly 75,000 dental offices.

UnitedHealthcare Military & Veterans. UnitedHealthcare Military & Veterans is the provider of health care services for nearly 3 million active duty and retired military service members and their families in 21 states

June 25, 2015**3:30 pm**

(West Region) under the Department of Defense's (DoD) TRICARE Managed Care Support contract. The contract began on April 1, 2013, and includes a transition period and five one-year renewals at the government's option.

UnitedHealthcare Military & Veterans' responsibility as a contractor is to augment the military's direct care system by providing managed care support services, provider networks, medical management, claims/enrollment administration and customer service.

UnitedHealthcare Medicare & Retirement

UnitedHealthcare Medicare & Retirement provides health and well-being services to individuals age 50 and older, addressing their unique needs for preventive and acute health care services, as well as services dealing with chronic disease and other specialized issues common among older individuals. UnitedHealthcare Medicare & Retirement is fully dedicated to serving this growing senior market segment, providing products and services in all 50 states, the District of Columbia and most U.S. territories. It has distinct pricing, underwriting, clinical program management and marketing capabilities dedicated to health products and services in this market.

UnitedHealthcare Medicare & Retirement offers a spectrum of risk-based Medicare products that may be purchased by individuals or on a group basis, including Medicare Advantage plans, Medicare Prescription Drug Benefit (Medicare Part D) and Medicare Supplement products that extend and enhance traditional fee-for-service coverage. UnitedHealthcare Medicare & Retirement services include care management and clinical management programs, a nurse health line service, 24-hour access to health care information, access to discounted health services from a network of care providers and administrative services.

Premium revenues from the Centers for Medicare & Medicaid Services (CMS) represented 29% of UnitedHealth Group's total consolidated revenues for the year ended December 31, 2014, most of which were generated by UnitedHealthcare Medicare & Retirement.

UnitedHealthcare Medicare & Retirement has extensive distribution capabilities and experience, including direct marketing to consumers on behalf of its key clients: AARP, the nation's largest membership organization dedicated to the needs of people age 50 and over, and state and U.S. government agencies. Products are also offered through employer groups and agent channels.

UnitedHealthcare Medicare & Retirement's major product categories include:

Medicare Advantage. UnitedHealthcare Medicare & Retirement provides health care coverage for seniors and other eligible Medicare beneficiaries primarily through the Medicare Advantage program administered by CMS, including Medicare Advantage HMO plans, preferred provider organization (PPO) plans, Point-of-Service plans, Private-Fee-for-Service plans and Special Needs Plans (SNPs). Under the Medicare Advantage program, UnitedHealthcare Medicare & Retirement provides health insurance coverage in exchange for a fixed monthly premium per member from CMS and in some cases consumer premiums. Premium amounts received from CMS vary based on the geographic areas in which members reside; demographic factors such as age, gender, and institutionalized status; and the health status of the individual. UnitedHealthcare Medicare & Retirement had approximately 3 million people enrolled in its Medicare Advantage products as of December 31, 2014.

Medicare Advantage plans are designed to compete at the local level, taking into account member and care provider preferences, competitor offerings, our historical financial results, our quality and cost initiatives and the long-term payment rate outlook for each geographic area. Starting in 2012, and phased in through 2017, the Medicare Advantage rate structure and quality rating bonuses are changing significantly. See Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" for further information.

UnitedHealthcare Medicare & Retirement offers innovative care management, disease management and other clinical programs, integrating federal, state and personal funding through its continuum of Medicare Advantage

products. For high-risk patients in certain care settings and programs, UnitedHealthcare Medicare & Retirement uses proprietary, automated medical record software that enables clinical care teams to capture and track patient data and clinical encounters, creating a comprehensive set of care information that bridges across home, hospital and nursing home care settings. Proprietary predictive modeling tools help identify members at high risk and allow care managers to reach out to those members and create individualized care plans that help them obtain the right care, in the right place, at the right time.

Medicare Part D. UnitedHealthcare Medicare & Retirement provides Medicare Part D benefits to beneficiaries throughout the United States and its territories through its Medicare Advantage and stand-alone Medicare Part D plans. UnitedHealthcare Medicare & Retirement offers two stand-alone Medicare Part D plans: the AARP MedicareRx Preferred and the AARP MedicareRx Saver Plus plans. The stand-alone Medicare Part D plans address a large spectrum of beneficiaries' needs and preferences for their prescription drug coverage, including low cost prescription options. Each of the plans includes the majority of the drugs covered by Medicare and provides varying levels of coverage to meet the diverse needs of Medicare beneficiaries. As of December 31, 2014, UnitedHealthcare enrolled approximately 8 million people in the Medicare Part D programs, including more than 5 million individuals in the stand-alone Medicare Part D plans and approximately 3 million in Medicare Advantage plans incorporating Medicare Part D coverage.

Medicare Supplement. UnitedHealthcare Medicare & Retirement is currently serving more than 4 million seniors through various Medicare Supplement products in association with AARP. UnitedHealthcare Medicare & Retirement offers plans in all 50 states, the District of Columbia, and most U.S. territories. UnitedHealthcare Medicare & Retirement offers a full range of supplemental products at diverse price points. These products cover the various levels of coinsurance and deductible gaps that seniors are exposed to in the traditional Medicare program.

UnitedHealthcare Community & State

UnitedHealthcare Community & State is dedicated to serving state programs that care for the economically disadvantaged, the medically underserved and those without the benefit of employer-funded health care coverage, in exchange for a monthly premium per member from the state program. In some cases, these premiums are subject to experience or risk adjustments. UnitedHealthcare Community & State's primary customers oversee Medicaid plans, Children's Health Insurance Programs (CHIP), SNPs, integrated Medicare-Medicaid plans (MMP) and other federal, state and community health care programs. As of December 31, 2014, UnitedHealthcare Community & State participated in programs in 24 states and the District of Columbia, and served more than 5 million beneficiaries. Health Reform Legislation provided for optional Medicaid expansion effective January 1, 2014. For 2015, 13 of our state customers have elected to expand Medicaid, an increase of one state since 2014. For further discussion of the Medicaid expansion under Health Reform Legislation, see Part II, Item 7, "Management Discussion and Analysis of Financial Condition and Results of Operations."

States using managed care services for Medicaid beneficiaries select health plans by using a formal bid process or by awarding individual contracts. A number of factors are considered by UnitedHealthcare Community & State when choosing programs for participation including the state's commitment and consistency of support for its Medicaid managed care program in terms of service, innovation and funding; the eligible population base, both immediate and long term; and the structure of the projected program. UnitedHealthcare Community & State works with its state customers to advocate for actuarially sound rates that are commensurate with medical cost trends.

The primary categories of eligibility for the programs served by UnitedHealthcare Community & State and our participation are:

- Temporary Assistance to Needy Families, primarily women and children – 21 markets;
- CHIP – 21 markets;

- Aged, Blind and Disabled (ABD) – 16 markets;
- SNP – 14 markets;
- Medicaid Expansion – 13 markets;
- Long-Term Services and Supports (LTSS) – 12 markets;
- other programs (e.g., developmentally disabled, rehabilitative services) – 6 markets
- childless adults programs for the uninsured – 4 markets; and
- MMP – 1 market.

These health plans and care programs offered are designed to address the complex needs of the populations they serve, including the chronically ill, those with disabilities and people with a higher risk of medical, behavioral and social conditions. UnitedHealthcare Community & State administers benefits for the unique needs of children, pregnant women, adults, seniors and those who are institutionalized or are nursing home eligible. They often live in areas that are medically underserved and are less likely to have a consistent relationship with the medical community or a care provider. These individuals also tend to face significant social and economic challenges.

UnitedHealthcare Community & State leverages the national capabilities of UnitedHealth Group locally, supporting effective care management, strong regulatory partnerships, greater administrative efficiency, improved clinical outcomes and the ability to adapt to a changing national and local market environment. UnitedHealthcare Community & State coordinates resources among family, physicians, other health care providers, and government and community-based agencies and organizations to facilitate continuous and effective care.

The LTSS market represents only 6% of the total Medicaid population, yet accounts for more than 30% of total Medicaid expenditures. The LTSS population is made up of over 4 million individuals who qualify for additional benefits under LTSS programs who represent a subset of the more than 16 million ABD Americans. Currently, only one-quarter of the ABD population and approximately 20% of the LTSS eligible population are served by managed care programs. States are increasingly looking for solutions to not only help control costs, but to improve quality for the complex medical challenges faced by this population and are moving with greater speed to managed care programs.

There are more than 9 million individuals eligible for both Medicare and Medicaid. This group has historically been referred to as dually eligible or MMP. MMP beneficiaries typically have complex conditions with costs of care that are far higher than typical Medicare or Medicaid beneficiaries. While these individuals' health needs are more complex and more costly, they have been historically served in unmanaged environments. This market provides UnitedHealthcare an opportunity to integrate Medicare and Medicaid funding and improve people's health status through close coordination of care.

Total annual expenditures for MMPs are estimated at more than \$390 billion, or approximately 13% of the total health care costs in the United States. As of December 31, 2014, UnitedHealthcare served more than 315,000 people with complex conditions similar to those in an MMP population in legacy programs through Medicare Advantage dual SNPs. As of December 31, 2014, UnitedHealthcare Community & State had been awarded new MMP business taking effect in 2015 in Ohio and Texas.

UnitedHealthcare Global

UnitedHealthcare Global participates in international markets through national "in country" and cross-border strategic approaches. UnitedHealthcare Global's cross-border health care business provides comprehensive health benefits, care management and care delivery for multinational employers, governments and individuals

June 25, 2015**3:30 pm**

around the world. UnitedHealthcare Global's goal is to create business solutions that are based on local infrastructure, culture and needs, and that blend local expertise with experiences from the U.S. health care industry. As of December 31, 2014, UnitedHealthcare Global provided medical benefits to more than 4 million people, principally in Brazil, but also residing in more than 125 other countries.

Amil. Amil provides health and dental benefits to nearly 7 million people. Amil operates more than 30 acute hospitals and approximately 50 specialty, primary care and emergency services clinics across Brazil, principally for the benefit of its members. Amil's patients are also treated in its contracted provider network of nearly 27,000 physicians and other health care professionals, approximately 2,100 hospitals and more than 7,600 laboratories and diagnostic imaging centers. Amil offers a diversified product portfolio with a wide range of product offerings, benefit designs, price points and value, including indemnity products. Amil's products include various administrative services such as network access and administration, care management and personal health services and claims processing.

Other Operations. UnitedHealthcare Global includes other diversified global health services operations with a variety of offerings for international customers, including:

- network access and care coordination in the United States and overseas;
- TPA products and services for health plans and TPAs;
- brokerage services;
- practice management services for care providers;
- government and corporate consulting services for improving quality and efficiency; and
- global expatriate insurance solutions.

Optum

Optum is a health services business serving the broad health care marketplace, including:

- Those who need care: the consumers who need the right support, information, resources and products to achieve their health goals.
- Those who provide care: pharmacies, physicians' practices, hospitals and clinical facilities seeking to modernize the health system and support the best possible patient care and experience.
- Those who pay for care: insurers, employers and government agencies devoted to ensuring the populations they sponsor receive high-quality care, administered and delivered efficiently.
- Those who innovate for care: life sciences and research focused organizations dedicated to developing more effective approaches to care, enabling technologies and medicines that improve care delivery and health outcomes.

Using advanced data analytics and technology, Optum helps improve overall health system performance by optimizing care quality, reducing costs and improving the consumer experience and care provider performance. Optum is organized in three reportable segments:

- OptumHealth focuses on care delivery, care management, consumer engagement, distribution and health financial services;
- OptumInsight delivers operational services and support and health information technology services; and
- OptumRx specializes in pharmacy services.

OptumHealth

OptumHealth is a diversified health and wellness business serving the physical, emotional and financial needs of more than 63 million unique individuals. OptumHealth enables population health management through programs offered by employers, payers, government entities and, increasingly, directly with the care delivery system. OptumHealth products and services deliver value by improving quality and patient satisfaction while lowering cost. OptumHealth works to optimize the care delivery system through the creation of high-performing networks and centers of excellence across the care continuum, by working directly with physicians to advance population health management and by focusing on caring for the most medically complex patients.

OptumHealth offers its products on a risk basis, where it assumes responsibility for health care costs in exchange for a monthly premium per individual served, and on an administrative fee basis, under which it manages or administers delivery of the products or services in exchange for a fixed fee per individual served. For its financial services offerings, OptumHealth charges fees and earns investment income on managed funds.

OptumHealth sells its products primarily through its direct sales force, strategic collaborations and external producers in three markets: employers (which includes the sub-markets of large, mid-sized and small employers), payers (which includes the sub-markets of health plans, TPAs, underwriter/stop-loss carriers and individual market intermediaries) and government entities (which includes states, CMS, DoD, the Veterans Administration and other federal procurement agencies). As provider reimbursement models evolve, care providers are emerging as a fourth market for the health management, financial services and local care delivery businesses.

OptumHealth is organized into two major operating groups: Collaborative Care and Consumer Solutions Group (CSG).

Collaborative Care. Collaborative Care's major product offerings include local care delivery, complex population management and mobile care delivery.

- **Local Care Delivery.** Local care delivery serves patients through a collaborative network of care providers aligned around total population health management and outcomes-based reimbursement. Within its local care delivery systems, OptumHealth works directly with medical groups and Independent Practice Associations to deploy a core set of technology, risk management, analytical and clinical capabilities and tools to assist physicians in delivering high-quality care across the populations they serve. OptumHealth is directly affiliated with clinics and physicians who provided care to more than 2 million patients in 2014.
- **Complex Population Management.** Complex population management services focus on improving care for patients with very challenging medical conditions by providing the optimal care in the most appropriate setting. Complex population management is focused on building and executing integrated solutions for payers, governmental agencies, accountable care organizations and provider groups for the highest cost patient segment of the health care system with focus on optimizing patient outcomes, quality and cost effectiveness. In addition, complex population management provides hospice services in 17 markets in the United States.
- **Mobile Care Delivery.** OptumHealth's mobile care delivery business provides occupational health, medical and dental readiness services, treatments and immunization programs. These solutions serve a number of government and commercial clients including the U.S. military.

CSG. CSG includes population health management services, specialty networks, distribution and financial services products.

- **Population Health Management Services:** OptumHealth serves nearly 38 million people through population health management services, including care management, complex conditions (e.g., cancer, neonatal and maternity), health and wellness and advocacy decision support solutions.

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- **Specialty Networks.** Within specialty networks, OptumHealth serves more than 57 million people by offering them access to proprietary networks of provider specialists in the areas of behavioral health management (e.g., mental health, substance abuse), chiropractic, physical therapy, transplant, infertility, kidney and end stage renal disease.
- **Distribution:** This business provides health exchange capabilities to help payers, market aggregators and employers meet the needs of the consumers they serve. OptumHealth provides call center support, multi-modal communications software, data analysis and trained nurses that help clients acquire, retain and service large populations of health care consumers.
- **Financial Services:** This business serves the health financial needs of individuals, employers, health care professionals and payers. OptumHealth is a leading provider of consumer health care accounts. OptumHealth also offers electronic payment solutions to manage compliance and improve the administrative efficiency of electronic claim payments. As of December 31, 2014, Financial Services and its wholly owned subsidiary, Optum Bank, had \$2.8 billion in customer assets under management and during 2014 processed \$85 billion in medical payments to physicians and other health care providers.

OptumInsight

OptumInsight provides technology, operational and consulting services to participants in the health care industry. Hospital systems, physician practices, commercial health plans, government agencies, life sciences companies and other organizations that constitute the health care system use OptumInsight to help them reduce costs, meet compliance mandates, improve clinical performance, achieve efficiency and modernize their core operating systems to meet the changing needs of the health system landscape.

Many of OptumInsight's software and information products, advisory consulting arrangements and outsourcing contracts are delivered over an extended period, often several years. OptumInsight maintains an order backlog to track unearned revenues under these long-term arrangements. The backlog consists of estimated revenue from signed contracts, other legally binding agreements and anticipated contract renewals based on historical experience that either have not started but are anticipated to begin in the near future, or are in process and have not been completed. OptumInsight's aggregate backlog at December 31, 2014, was \$8.6 billion, of which \$4.8 billion is expected to be realized within the next 12 months. This includes \$2.9 billion related to intersegment agreements, all of which are included in the current portion of the backlog. OptumInsight's aggregate backlog at December 31, 2013, adjusted for the January 1, 2014 business realignment discussed in Note 13 of Notes to Consolidated Financial Statements included in Part II, Item 8, "Financial Statements," was \$7.5 billion including \$2.7 billion related to intersegment agreements. The increase in 2014 backlog was attributable to a revenue management services acquisition and general business growth, partially offset by services performed on existing contracts. OptumInsight cannot provide any assurance that it will be able to realize all of the revenues included in the backlog due to uncertainties with regard to the timing and scope of services and the potential for cancellation, non-renewal or early termination of service arrangements.

OptumInsight's products and services are sold primarily through a direct sales force. OptumInsight's products are also supported and distributed through an array of alliances and business partnerships with other technology vendors, who integrate and interface OptumInsight's products with their applications.

OptumInsight provides capabilities targeted to the needs of four primary market segments: care providers (e.g., physician practices and hospitals), payers, governments and life sciences organizations.

Care Providers. Serving four out of five U.S. hospitals and tens of thousands of physician practices, OptumInsight provides capabilities that help drive financial performance, meet compliance requirements and deliver health intelligence. OptumInsight's offerings in clinical workflow software, revenue management tools and services, health IT and analytics help hospitals and physician practices improve patient outcomes, strengthen financial performance and meet quality measurement and compliance requirements, as well as transition to new collaborative and value based business models.

June 25, 2015**3:30 pm**

Payers. OptumInsight serves approximately 300 health plans by helping them improve operational and administrative efficiency, meet clinical performance and compliance goals, develop strong provider networks, manage risk and drive growth. OptumInsight also helps payer clients adapt to new market models, including health insurance exchanges, consumer driven health care and engagement, pay-for-value contracting and population health management.

Governments. OptumInsight provides services to government agencies across 36 states and the District of Columbia. Services include financial management and program integrity services, policy and compliance consulting, data and analytics technology, systems integration and expertise to improve medical quality, access and costs.

Life Sciences. OptumInsight's Life Sciences business provides services to more than 200 global life sciences organizations. OptumInsight's services use real-world evidence to support market access and positioning of products, provide insights into patient reported outcomes and optimize and manage risk.

OptumRx

OptumRx provides a full spectrum of pharmacy benefit management (PBM) services to more than 30 million Americans nationwide, managing more than \$40 billion in pharmaceutical spending annually and processing nearly 600 million adjusted retail, home delivery and specialty drug prescriptions annually. OptumRx's PBM services deliver a low cost, high-quality pharmacy benefit through retail network contracting services, home delivery and specialty pharmacy services, manufacturer rebate contracting and management and a variety of clinical programs such as step therapy, formulary management, drug adherence and disease and drug therapy management programs. As of December 31, 2014, OptumRx's network included more than 67,000 retail pharmacies and two home delivery pharmacy facilities in California and Kansas.

The home delivery and specialty pharmacy fulfillment capabilities of OptumRx are an important strategic component of its business, providing patients with convenient access to maintenance medications, offering a broad range of complex drug therapies and patient management services for individuals with chronic health conditions and enabling OptumRx to help consumers achieve optimal health, while maximizing cost savings.

OptumRx provides PBM services to a substantial majority of UnitedHealthcare members. Additionally, OptumRx manages specialty pharmacy benefits across nearly all of UnitedHealthcare's businesses with services including patient support and clinical programs designed to ensure quality and deliver value for consumers. This is crucial in managing overall drug spend, as biologics and other specialty medications are the fastest growing pharmacy expenditures. OptumRx also provides PBM services to non-affiliated external clients, including public and private sector employer groups, insurance companies, Taft-Hartley Trust Funds, TPAs, managed care organizations (MCOs), Medicare-contracted plans, Medicaid plans and other sponsors of health benefit plans and individuals throughout the United States. OptumRx's distribution system consists primarily of health insurance brokers and other health care consultants and direct sales.

GOVERNMENT REGULATION

Most of our health and well-being businesses are subject to comprehensive federal, state and international laws and regulations. We are regulated by federal, state and international regulatory agencies that generally have discretion to issue regulations and interpret and enforce laws and rules. The regulations can vary significantly from jurisdiction to jurisdiction, and the interpretation of existing laws and rules also may change periodically. Domestic and international governments continue to enact and consider various legislative and regulatory proposals that could materially impact certain aspects of the health care system. New laws, regulations and rules, or changes in the interpretation of existing laws, regulations and rules, including as a result of changes in the political climate, could adversely affect our business.

C, Orderly Development--7(C) Licensing & Accreditation Inspections

Board for Licensing Health Care Facilities

State of  Tennessee

License No. 0000000471

DEPARTMENT OF HEALTH

This is to certify, that a license is hereby granted by the State Department of Health to

ALERE WOMEN'S AND CHILDREN'S HEALTH, LLC

to conduct and maintain a

Home Care Organization

ALERE WOMEN'S AND CHILDREN'S HEALTH, LLC

Located at

1926 HAYES STREET, SUITE 111, NASHVILLE

County of

DAVIDSON

, Tennessee.

This license shall expire

FEBRUARY 11

2016

, and is subject to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable, and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the State Department of Health issued thereunder.

In Witness Whereof, we have hereunto set our hand and seal of the State this 13TH *day of* JANUARY *, 2015.*

In the District Category(ies) of:

SKILLED NURSING
HOME HEALTH AGENCY



By

Timothy J. Davis, MPH
DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

By

John J. Dyer
COMMISSIONER

July 17, 2013

Mike Cotton
Chief Executive Officer
Alere Women's and Children's Health, LLC
3200 Windy Hill Road, Suite B-100
Atlanta, GA 30339

Joint Commission ID #: 436425
Program: Home Care Accreditation
Accreditation Activity: 60-day Evidence of
Standards Compliance
Accreditation Activity Completed: 07/17/2013

Dear Mr. Cotton:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

- Comprehensive Accreditation Manual for Home Care

This accreditation cycle is effective beginning May 15, 2013. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,



Mark G. Pelletier, RN, MS

Chief Operating Officer

Division of Accreditation and Certification Operations

**COPY**

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
WEST TENNESSEE REGIONAL OFFICE
HEALTH CARE FACILITIES
2975 C Highway 45 Bypass
Jackson, Tennessee 38305
Telephone: (731) 984-9684

December 10, 2014

Ms. Laura Milner, Administrator
Alere Women's and Children's Health
1926 Hayes Street
Nashville, TN 37203

RE: Licensure Survey – TNHL004 Dated 12/2/2014

Dear Ms. Milner:

We are pleased to advise you that no deficiencies were cited as a result of an annual licensure survey conducted at your facility on December 02, 2014. A copy of the survey is enclosed for your files.

If this office may be of any assistance to you, please feel free contact us.

Sincerely,

Diane Carter

Diane Carter, RN, LNCC
Public Health Nurse Consultant 2

DC/gk *gk*

Enclosure

JUN 15 10 09:42 AM '14

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNHL004	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 12/02/2014
NAME OF PROVIDER OR SUPPLIER ALERE WOMEN'S AND CHILDREN'S HEALTH,			STREET ADDRESS, CITY, STATE, ZIP CODE 1926 HAYES STREET NASHVILLE, TN 37203		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 002	1200-8-26 No Deficiencies. This Rule is met as evidenced by: The agency was found to be in compliance with state regulations for Home Health during the licensure survey conducted on 12/2/14. No deficiencies were cited.	H 002			

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE



July 17, 2013

Mike Cotton
Chief Executive Officer
Alere Women's and Children's Health, LLC
3200 Windy Hill Road, Suite B-100
Atlanta, GA 30339

Joint Commission ID #: 436425
Program: Home Care Accreditation
Accreditation Activity: 60-day Evidence of
Standards Compliance
Accreditation Activity Completed: 07/17/2013

Dear Mr. Cotton:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

- Comprehensive Accreditation Manual for Home Care

This accreditation cycle is effective beginning May 15, 2013. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,

Mark G. Pelletier, RN, MS

Chief Operating Officer

Division of Accreditation and Certification Operations

Evaluation of Alere compared to Alere's Mission

1. Excellent care coordination between field and call center
2. Sharing of information between regions
3. Positive comments from patients regarding field nurses and call center staff
4. Competency of co-travel (suggested we submit as a best practice)
5. Effectiveness of contracted central pharmacy
6. Coordination of care between the pharmacy (contract agency) and home care organization
7. Illinois manager participated in survey despite personal loss
8. Ability of patient to provide therapy on an ongoing basis (patients are being provided the tools for self- management)
9. Teaching/follow-up tools provided to patients for self-management

Alere Women's and Children's Health, LLC
3200 Windy Hill Road, Suite B-100
Atlanta, GA 30339

Organization Identification Number: 436425

Evidence of Standards Compliance (60 Day) Submitted: 7/11/2013

Program(s)
Home Care Accreditation

Executive Summary

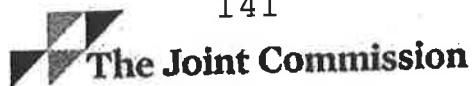
Home Care Accreditation : As a result of the accreditation activity conducted on the above date(s), there were no Requirements for Improvement identified.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

**The Joint Commission
Summary of Compliance**

Program	Standard	Level of Compliance
OME	EM.03.01.03	Compliant
OME	IM.02.01.01	Compliant
OME	MM.05.01.09	Compliant



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Alere Women's and Children's Health, LLC
3200 Windy Hill Road, Suite B-100
Atlanta, GA 30339

Organization Identification Number: 436425

Program(s)
Home Care Accreditation

Survey Date(s)
05/07/2013-05/07/2013, 05/08/2013-05/10/2013, 05/13/2013-
05/14/2013, 05/16/2013-05/16/2013, 05/22/2013-05/22/2013

Executive Summary

**Home Care
Accreditation :**

As a result of the accreditation activity conducted on the above date(s), Requirements for Improvement have been identified in your report.

You will have follow-up in the area(s) indicated below:

- Evidence of Standards Compliance (ESC)

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

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**The Joint Commission
Summary of Findings**

Evidence of **DIRECT** Impact Standards Compliance is due within 45 days from the day the survey report was originally posted to your organization's extranet site:

Program:	Home Care Accreditation Program	
Standards:	PC.02.01.01	EP2

Evidence of **INDIRECT** Impact Standards Compliance is due within 60 days from the day the survey report was originally posted to your organization's extranet site:

Program:	Home Care Accreditation Program	
Standards:	EM.03.01.03	EP1
	IM.02.01.01	EP2
	MM.05.01.09	EP2

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**The Joint Commission
Findings**

Chapter: Emergency Management
Program: Home Care Accreditation
Standard: EM.03.01.03

ESC 60 days

Standard Text: The organization evaluates the effectiveness of its Emergency Operations Plan.

Primary Priority Focus Area: Communication

Element(s) of Performance:

1. The organization activates its Emergency Operations Plan once a year at each site included in the plan, either in response to an actual emergency or as a planned exercise.



Note: Planned exercises should focus on the organization's response to an emergency that is likely to affect continuation of care, treatment, or services. Exercises do not need to be conducted in each community served by the organization but should be based on a regional or county response strategy where applicable. Exercises that involve substitutes for patients (such as pillows, bundles, mannequins, or live volunteers) are acceptable.

Scoring

Category : A
Score : Insufficient Compliance

Observation(s):

EP 1

Observed in Document Review at Alere Women's and Children's Health, LLC (6525 E 82nd St. Suite 101, Indianapolis, IN) site.

During the document review the home care surveyor observed the organization did not include patients or a substitute for patients in its 2012 emergency operations drill. The drill's activity was a bomb threat to the home care office building. Discussion with leadership confirmed the scope of the drill did not include its patients or field staff.

Chapter: Information Management
Program: Home Care Accreditation
Standard: IM.02.01.01

ESC 60 days

Standard Text: The organization protects the privacy of health information.

Primary Priority Focus Area: Information Management

Element(s) of Performance:

2. The organization implements its policy on the privacy of health information. (See also RI.01.01.01, EP 7)



Scoring

Category : A
Score : Insufficient Compliance

Observation(s):

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**The Joint Commission
Findings**

EP 2

Observed in Tracer Visit at Alere Women's and Children's Health, LLC (877 Franklin Rd. Suite 205, Marietta, GA) site.

During tracer visit #4 to a patient receiving initiation of infusion services for hydration and SQ Ondansetron the surveyor observed the skilled nurse place the outer wrapper of the infusion bag for D5/LR into a box to be placed in the trash. The bag wrapper contained the prescription label with the patient's name, infusion instructions, physician, etc. Review of agency policies HIPAA 15.1 and QI-017 indicated that processes were in place to protect the privacy of PHI from unauthorized or inappropriate use by discarding in a container for shredding.

Observed in Individual Tracer at Alere of New York, Inc. (19-02 Whitestone Expressway #402, Whitestone, NY) site.

At a Whitestone home visit to initiate continuous SQ Ondansetron therapy a loading dose was administered IM. The skilled nurse used the zip lock bag that had housed the medication for the loading dose as her "garbage bag" for alcohol preps, paper, etc. The zip lock bag contained the medication label as well as patient information. This bag was then to be placed in the garbage. Organization policies indicated that processes were in place to protect PHI information though not implemented on this visit.

Chapter: Medication Management

Program: Home Care Accreditation

Standard: MM.05.01.09

ESC 60 days

Standard Text: Medications are labeled.
Note: This standard is applicable to all organizations that prepare and administer medications.

Primary Priority Focus Area: Medication Management

Element(s) of Performance:

2. Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.



Scoring

Category : A

Score : Insufficient Compliance

Observation(s):

145
**The Joint Commission
Findings**

EP 2

Observed in Tracer Visit at Alere Women's and Children's Health, LLC (877 Franklin Rd. Suite 205, Marietta, GA) site.

During tracer visit #1 to a new patient for setup of SQ Ondansetron infusion it was noted that the labels on three pre-filled medication syringes did not contain an expiration date for the medication contained in the syringes. These pre-filled syringes were prepared at the local Smyrna, Ga. Pharmarica pharmacy and delivered to the patient for use for first dose. The outer bag which contained the pre-filled syringes also did not contain an expiration date for the medication. The nurse did not administer this medication and it was destroyed. The patient received the prescribed dose of medication from another bag of medication which was issued by the main Pharmarica pharmacy that was correctly labeled. Additionally, there were no lot numbers on either the syringe labels or the packaging labels. Review of the syringes from the main pharmacy included expiration dates and lot numbers.

Observed in Tracer Visit at Alere Women's and Children's Health, LLC (877 Franklin Rd. Suite 205, Marietta, GA) site.

During tracer visit #4 it was noted that for this patient receiving infusion hydration services the outer packaging of the IV bag was labeled with the patient's name, rx. number, infusion instructions, physician, etc. however the bag actual bag of D5/LR solution was hung and infusing without a label. Review of a Pharmarica generated memo presented by leadership stated that IV bags were to be removed from the outer packaging and the label was to be applied to the actual bag by the local pharmacy prior to delivery. The leadership stated that the local pharmacy that prepared the IV delivery for this patient was a relatively new affiliate Pharmarica pharmacy and may have been unaware of the process identified in the memo.

Chapter: Provision of Care, Treatment, and Services

Program: Home Care Accreditation

Standard: PC.02.01.01

ESC 45 days

Standard Text: The organization provides care, treatment, or services for each patient.

Primary Priority Focus Area: Assessment and Care/Services

Element(s) of Performance:

2. Staff provide care, treatment, or services in accordance with professional standards of practice, law, and regulation.



Scoring

Category : A

Score : Insufficient Compliance

Observation(s):

EP 2

Observed in Individual Tracer at Alere Women's and Children's Health, LLC (6525 E 82nd St. Suite 101, Indianapolis, IN) site.

During a home visit (HV2) the home care surveyor observed the clinician did not provide care in accordance with professional standards and organizational policy. During the process of injecting 17P IM the clinician did not aspirate prior to administering the medication. The clinician used her left hand to isolate and hold the injection site while using the right hand to perform the stick and inject the medication. Discussion with leadership and review of policy confirmed aspirations are required prior to injecting medications.

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

Alma Women's & Children's Health, LLC

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.



John L Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 25th day of June, 2015,
witness my hand at office in the County of DAVIDSON, State of Tennessee.

Jan M. Danforth
NOTARY PUBLIC

My commission expires July 2, 2018

SUPPLEMENTAL #1

June 25, 2015

3:30 pm

June 24, 2015

Jeff Grimm, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1506-025
Alere Women's and Children's Health

Dear Mr. Grimm:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. Section A, Applicant Profile, Item 3

a. The documentation of ownership, including registration in Tennessee and a copy of an organization chart, is noted. Who are the members of the LLC with ownership interests of 5% or more? Does the applicant intend to expand the ownership of the LLC in the future?

There are no individuals with membership interests in the applicant LLC. There are no plans to expand its ownership in the future. As stated in the application on page 5 (Executive Summary), Alere Women's and Children's Health, LLC is a wholly owned subsidiary Alere Health, LLC, which is wholly owned by OptumHealth Care Solutions, Inc., which is ultimately owned by United Health Group, a publicly traded company.

b. Given the ownership interests by Optum Healthcare Solutions and United Health Group, what additional insight can the applicant provide about the nature & scope of their ownership interests in similar home health service organizations and healthcare facilities in the United States?

United Health Group is a very large publicly traded company with multiple divisions and services. At the end of this response letter are company profile sections of its Form 10K report, describing its array of companies and services. The only home health care entity it owns directly or indirectly is Alere Women's and Children's Health, LLC. It owns no licensed physical facilities such as hospitals or nursing homes. Alere Women's and Children's Health, LLC has home health agencies licensed in twenty States.

June 25, 2015**3:30 pm**

Page Two
June 24, 2015

c. The address for Alere Women's and Children's Health LLC is noted as 3200 Windy Hill Rd in Atlanta, Georgia for both the Hamilton and Shelby County agencies on the TDH licensure website which differs from the Nashville address for the applicant. As such, the different addresses create some confusion about the ownership relationship between the parties. Please explain.

The applicant does not know why the TDH licensure website is inaccurate in that regard. In January of this year, Alere submitted its annual renewal information with accurate local office addresses for its agencies. Attached after this page are copies of the Alere TDH filing showing this Agency's correct local address.

d. Review of the correspondence from the Delaware Secretary of State's Office provided in the ownership attachments revealed that an entity named Artemis Merger, LLC merged with and Matria Healthcare, LLC under the name of Alere LLC effective December 31, 2008. Since this ownership change was not addressed in the "Notes on Alere Women's and Children's Health LLC", please clarify how this fits into the organizational profile of the applicant.

The transaction noted above relates to Alere Women's and Children's Health, LLC's direct parent company, Alere Health, LLC, but not to the applicant itself. As you note, Artemis Merger, LLC merged with and into Matria Healthcare, LLC under the name Alere LLC, which then changed its name to Alere Health, LLC.

2. Section A, Applicant Profile, Item 6 and Section B, Project Description, Item IV (Floor Plan)

a. The documentation of site control (lease) is noted. Based on the amendment to the original lease, it appears that the lease will expire in June 2015. Please provide additional documentation that confirms the applicant will hold a legal interest in the site at the time the application is heard by the Agency Board Members in September 2015.

The newly signed lease extension is attached after this page, following the correspondence referenced in question 1c above.



3200 Windy Hill Road, Suite B-100
Attention: Regulatory Affairs
Atlanta, GA 30339

919 571 6732 Home Office
770 767 8218 O
770 916 1312 F

June 25, 2015
3:30 pm
DOCUMENTATION
OF
AGENCY
ADDRESS

FEDERAL EXPRESS

January 7, 2015

State of Tennessee
Department of Health
Division of Health Licensure and Regulation
Office of Health Care Facilities
665 Mainstream Drive, Second Floor
Nashville, TN 37243

Re: **Alere Women's and Children's Health, LLC License No. 0000000471**

Dear Sir/Madam:

Please accept the attached *Home Health Agency Renewal Application* and supporting documentation for Alere Women's and Children's Health, LLC ("Alere") located at 1926 Hays Street, Nashville, TN 37203. Please note in response to Question 4 the list of locations with addresses is printed in the JCAHO Report. Additionally attached is check no. 400861 in the amount of One Thousand Eighty Dollars (\$1080.00) as renewal fee.

Should you have any questions or require additional documentation please contact me at (919) 571-6732; 770-767-8218 or fern.matthews@alere.com.

Sincerely,

A handwritten signature in black ink that reads "Fern Matthews". The signature is written in a cursive, flowing style.

Fern Matthews
Director, Regulatory Affairs

Enclosure(s)

June 25, 2015**3:30 pm**

**STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH CARE FACILITIES
665 MAINSTREAM DRIVE, SECOND FLOOR
NASHVILLE, TENNESSEE 37243
(615) 741-7221**

**HOME HEALTH AGENCY
APPLICATION FOR INITIAL LICENSURE**

All applicable laws, rules, policies, and guidelines affecting your practice are available for viewing at www.state.tn.us/health. Please check this website periodically for updates.

Name of the Facility/Agency Alere Women's and Children's Health, LLC

Location of the Facility:

Street 1926 Hays Street City Nashville
County Davidson State Tennessee Zip 37203
Phone Number (615) 320-3270 Fax Number (615) 320-3271
Twenty-four (24) Hour Emergency Phone Number (615) 945-9148
E-Mail Address fern.matthews@alere.com

Administrator Information:

Administrator Laura Milner

Have you (Administrator) ever been convicted of a crime involving injury or harm to person(s), financial or business management (e.g., assault, battery, robbery, embezzlement or fraud)? Yes ☐ No ☒

If yes, what charge(s)? _____

Location of Conviction _____ Date _____
(City) (County) (State)

Mailing address if different from the Facility location address:

Name Alere Women's and Children's Health, LLC
Street 3200 Windy Hill Rd., Suite B-100 (Attn: Regulatory Affairs)
City Atlanta State GA Zip 30339

Ownership of Building:

Name Jack Gaw Phone Number (615) 321-0700
Street 1926 Hays Street
City Nashville State TN Zip 37203

FEE SCHEDULE: (FEES ARE NON-REFUNDABLE) \$1,080
PH-3506 (REV 11/13)

RDA-1165

June 25, 2015**3:30 pm**

1. Check type: Hospital Based _____ Nursing Home Based _____ Free Standing _____
2. Check type: Licensed only Agency ☒ Licensed/Medicaid Certified _____
3. Geographic area served by Agency: (list county or counties) *If additional space is needed, please use a separate page.*
 Bedford, Cheatham, Davidson, Dickson, Hickman, Houston, Marshall, Maury, Montgomery, Robertson, Rutherford, Sumner, Williamson, Wilson

4. Check type of services provided:

- | | | | |
|----------------------------|-------------------------------------|------------------------------------|-------|
| a. Skilled Nursing | <input checked="" type="checkbox"/> | f. Home Health Aid Services | _____ |
| b. Physical Therapy | _____ | g. Medical Supplies and Appliances | _____ |
| c. Occupational Therapy | _____ | h. Homemaker Services | _____ |
| d. Speech Therapy | _____ | i. Other (please specify) | _____ |
| e. Medical Social Services | _____ | | |

5. Number of branch offices: 0Address of each branch office: *(If additional space is needed, please use a separate page)***OWNERSHIP OF BUSINESS:**

1. a. Check the type of Legal Entity:

_____ Individual _____ Partnership _____ Corporation ☒ Limited Liability Company

_____ Church Related _____ Government/County _____ Other

b. Check one: ☒ For Profit _____ Non-profit

c. Legal Entity checked in 1.a:

Name Alere Health, LLC Phone Number (770) 767-4500Address 3200 Windy Hill Rd., Suite B-100 Atlanta, GA 30339

d. List name(s) and address(es) of individual owners, partners, directors of the corporation, or head of the governmental entity:

See Attached List

Name	Street	City, State, Zip
------	--------	------------------

Name	Street	City, State, Zip
------	--------	------------------

(If additional space is needed, please use a separate sheet)

2. a. Is your facility/organization accredited by a federally approved accrediting body (i.e., JCAHO, CARF, etc)?

Yes ☒ No _____ Expiration Date May 2016

b. Is your facility/organization deemed by a federally approved accrediting body? (i.e., JCAHO, CARF, etc)?

Yes _____ No _____ Expiration Date _____

June 25, 2015**3:30 pm**

3. If you have a parent company please provide the following information:

Name Alere Health, LLC

Phone Number

(770) 767-4500

Address 3200 Windy Hill Rd., Suite B-100 Atlanta, GA 30339

4. a. Are any owners of the disclosing entity also owners of other health care facilities in Tennessee and/or other states? Yes ☒ No ☐

- b. If yes, list names and addresses of all such facilities:

Alere Health, LLC is the parent company for Alere Women's and Children's Health, LLC facilities nationwide.

Please see the attached list.

5. a. Do you have a contract with a management firm to operate this facility? Yes ☐ No ☒

If yes, specify dates: From _____ To _____

- b. If yes, please specify name of firm: _____

Phone Number () _____

City, State, Zip

Street

6. a. Have any owners of the disclosing entity ever been denied a license, had a license suspended or revoke, had a suspension of admissions or paid any civil monetary penalties for a health care facility in Tennessee or in any other state? Yes ☐ No ☒

If yes, where? _____ When? _____

For what reason? _____

VERIFICATION BY NOTARY PUBLIC:

Signee for application certifies that he or she is of responsible character and able to comply with the minimum standards and regulations established by Tennessee pertaining to the type of facility or agency for which application for licensure is made and with the rules promulgated under Tennessee Code Annotated (TCA) § 68-11-201.

Signee also certifies that a policy has been implemented to inform all employees of their obligation under TCA § 71-6-103 to report incidents of abuse or neglect.

Applicant Signature

Secretary

Title or Position

Date

STATE GEORGIA

County of Cobb

The above named applicant (print name) Jeanne Shingleton, being by me duly sworn on his/her oath, deposes and says that he/she has read the forgoing application and knows the contents thereof: that the statements concerning the above named facility or agency, therein contained, are correct and true to his/her own knowledge.

Subscribed to and sworn to on this 5th day of JANUARY 2015

(Month)

(Year)

Notary Public:

Eva Savage

My commission expires:

3/15/2017

June 25, 2015**3:30 pm****LEASE EXTENSION AGREEMENT**

RE: 1926 Hayes Street
Nashville, TN 37203

The Lease Agreement between **Alere Women's and Children's Health, LLC.** and **Jack L. Gaw, DMD** at the above referenced location is scheduled to terminate June 30, 2015. Execution of this Lease Extension Addendum to the Lease Agreement will extend the term from **July 1, 2015 - June 30, 2016.**

All terms and conditions under the Lease Agreement remain unchanged, and the Monthly Lease Rate of [REDACTED] also will remain unchanged.

Please [REDACTED] two signed original executed copies of this Lease Extension Agreement to my [REDACTED] office. Upon full execution, I will return an original to you.

Regards,

Jack L. Gaw, DMD

Lease Extension Execution:



Alere Women's and Children's Health, LLC.

6/18/15
Date



Jack L. Gaw, DMD

6.22.15
Date

June 25, 2015**3:30 pm**

Page Three
June 24, 2015

b. Please also provide a floor plan for the parent office in Nashville.

The applicant has no floor plan of the interior of its office. A waiver of this requirement is requested because the principal office is not part of this application: no change of county location is being proposed; no change of location within the county is being proposed; no modification of the premises is being proposed. The applicant would have to engage an architect or draftsman to develop a floor plan.

3. Section A, Applicant Profile, Item 12

HSDA staff is aware that home health agencies in Tennessee need Medicare certification in order to participate in TennCare MCOs. However, the comments indicate that Medicare certification is not necessary for the reasons provided. With a TennCare payor mix of approximately 48% or higher, what sort of exemption or waiver did the applicant receive from TennCare in this regard?

This will be submitted under separate cover after conclusion of legal research.

4. Section B, Project Description, Item II

Discussion of the development of the proposal is noted. Please provide the following additional information for the highlights noted in this section of the application:

a. Have there been any changes in the applicant's scope of services from original CON approved in Matria Healthcare, Inc.-Nashville, CN9807-043A leading to licensure by TDH on March 1, 1999? Please discuss.

No. As new home care technologies and services are developed to deliver home healthcare, they may be utilized by Alere. But such clinical decisions remain under the scope of home health care as approved by the CON Board originally, and as defined by statute and State rules and regulations.

b. Please identify the specific home health skilled nursing services that correspond to the "Scope of Services" described on pages 10 and 11 and other parts of the application.

There is no service described in that section that is not delivered by Alere's visiting skilled nurse. They are all "skilled nursing services" for purposes of the law and regulations, and for reimbursement purposes. Alere sends no staff to a patient residence who is not an OB RN, skilled in this particular type of home care.

June 25, 2015**3:30 pm**

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June 24, 2015

c. Of the services identified, approximately what percentage could be classified as skilled nursing?

All of them are, by definition, because they are being delivered by an RN skilled in these services, and reimbursed by payers who define this care as skilled care.

d. In your response, please identify the minimum skilled nursing activities that must be provided as a condition of HHA licensure in Tennessee such as taking & recording patient vital signs and drawing blood and other fluids for lab tests.

Attached after this page is a copy of applicable parts of State licensure regulations.

e. Please clearly identify the key responsibilities of the patient's physician and the applicant's clinical staff, including the Director of Nurses, OB pharmacist, staff OB registered nurses and others to support the care of high risk obstetrical patients and newborns with antepartum and postpartum needs.

The patient's physician is the physician of record and refers the patient to Alere for the service required to manage the specific pregnancy-related condition requiring home care services. The physician provides the plan of treatment and oversees the care of the patient during her course of therapy.

The OB Pharmacist is available as a consultant to the physician to assist with questions surrounding medication use in pregnancy, advises on dosages of medication, safety of medications, reviews drug to drug interactions, and makes recommendations on concomitant use of medications.

The Director of nurses is responsible for Home Care Operations and supervision of all nursing and administrative functions associated with the operations of the Home Care facility. The Director of Nurses is responsible for maintaining all regulatory and Joint Commission standards.

Registered Nurses – Both Patient Educators (nurses that provide direct skilled nursing care in the home), and Perinatal Clinicians (nurses that provide telephonic management of the patient) are nurses with an active license in the state of Tennessee. All Registered Nurses employed by Alere have at least one year of high risk Obstetrical Experience, and all are capable to provide maternal-fetal assessments including the use of dopplers to assess fetal heart tones during the skilled nursing visits. These highly skilled nurses are well educated and versed in the management of the complexities surrounding diagnoses specific to the condition of pregnancy, which require a high level of skill and knowledge.

STANDARDS FOR HOMECARE ORGANIZATIONS PROVIDING HOME HEALTH SERVICES

(Rule 1200-08-26-.06, continued)

(5) Skilled Nursing Services.

- (a) The agency shall provide skilled nursing services by or under the supervision of a registered nurse who has no current disciplinary action against his/her license, in accordance with the plan of care. This person shall be available at all times during operating hours and participate in all activities relevant to the professional home health services provided, including the development of qualifications and assignment of personnel.
- (b) The registered nurse's duties shall include but are not limited to the following: make the initial evaluation visit, except in those circumstances where the physician has ordered therapy services as the only skilled service; regularly evaluate the patient's nursing needs; initiate the plan of care and necessary revisions; provide those services requiring substantial specialized nursing skill; initiate appropriate preventive and rehabilitative nursing procedures; prepare clinical and progress notes; coordinate services; inform the physician and other personnel of changes in the patient's condition and needs; counsel the patient and family in meeting nursing and related needs; participate in in-service programs; supervise and teach other nursing personnel. The registered nurse or appropriate agency staff shall initially and periodically evaluate drug interactions, duplicative drug therapy and non-compliance to drug therapy.
- (c) The licensed practical nurse shall provide services in accordance with agency policies, which may include but are not limited to the following: prepare clinical and progress notes; assist the physician and/or registered nurse in performing specialized procedures; prepare equipment and materials for treatments; observe aseptic technique as required; and assist the patient in learning appropriate self-care techniques.
- (d) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:
 - 1. The deceased was receiving the services of a licensed home care organization;
 - 2. The death was anticipated, and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present with the deceased at the place of death;
 - 3. The nurse is licensed by the state; and
 - 4. The nurse is employed by the home care organization providing services to the deceased.

(6) Therapy Services.

- (a) All therapy services offered by the agency directly or under arrangement shall be planned, delegated, supervised or provided by a qualified therapist in accordance with the plan of care. A qualified therapist assistant may provide therapy services under the supervision of a qualified therapist in accordance with the plan of care. The therapist shall assist the physician in evaluating the level of function, helping develop the plan of care (revising as necessary), preparing clinical and progress notes, advising and consulting with the family and other agency personnel, and participating in in-service programs.
- (b) Speech therapy services shall be provided only by or under supervision of a qualified speech language pathologist or audiologist in good standing.

June 25, 2015**3:30 pm**

Page Five

June 24, 2015

f. Please provide the names and brief description of the experience and qualifications of the applicant's Medical Director and Director of Nursing.

Laura Milner, RN, BSN, is Alere/Davidson County's Home Care Director. She has 20 years of nursing experience, 17 years of which are related to the field of Obstetrics. Laura has been a Home Care Director for 10 years with Alere, and has successfully passed all State Surveys and Joint Commission surveys. This position is equivalent to the Director of Nursing position for this agency.

Alere home health agencies do not require a local Medical Director because they work under the direction of the patients' physicians, with whom they are in continuous contact. Nationally, the Alere Medical Director is Norman Ryan, MD. His extensive CV is attached at the end of this letter.

g. Has the applicant collaborated with existing home health agencies, Department of Health maternal and child health programs and professional home health association(s) to identify and assess the need for its specialty in-home services for high risk women and their newborns in the 22 counties being requested in this proposal?

Alere has not discussed area needs with the State's maternal and child health programs.

With regard to collaboration discussions with other home health agencies, if optimal patient outcomes could be assured, Alere would be willing and able to provide this specialty care on a subcontracting basis, and has done so in the past. But Alere ceased to subcontract under general home health agencies years ago, because of difficulty with controlling the scope and costs of care in a manner that optimized good outcomes. This is an area with serious liability risks and Alere is not willing to share control of patient care with another party that is inexperienced in that care.

June 25, 2015**3:30 pm**

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June 24, 2015

h. Were any existing service providers identified in the assessment? If so, why aren't these arrangements working in the proposed 22 counties?

Alere is not aware of any agency in the area that provides the same level of care to the same patient population in all 22 counties of the proposed service area, either directly or through subcontracting. At staff's request, further research into that question is now being conducted by Alere staff through sampling of existing agencies. Please see the response to question #7 below for additional information.

i. Please describe the applicant's planning and research efforts in this regard in preparing for the development of its certificate of need application.

Alere's information on area needs comes from its contacts with insurers (including TennCare MCO's) and physicians who express that there is a need for their patients in the proposed service area. These payers are reliably in touch with area needs.

j. In your response, please include any documentation from representatives indicating their participation in preparing an assessment of the need for the applicant's unique services in the additional 22 counties.

There is no such information to offer at this time.

k. Of the programs noted on page 10 under Scope of Services, what services qualify as skilled nursing services of home health agencies?

As stated above, all of them do, when delivered by a skilled OB RN.

June 25, 2015**3:30 pm**

Page Seven
June 24, 2015

l. Is there a skilled nursing service that would also involve support for pregnant women with drug addictions related to recent legislation in Tennessee and program priorities by the state Department of Health? Please include a brief overview of same.

Tennessee recently enacted Public Chapter 820 regarding Neonatal Abstinence Syndrome, or NAS. A TDH FAQ with an overview of that law, dated 6-24-2014, is attached following this page.

The law does not pertain to Alere's services. It affects reporting requirements at the time of birth, which takes place in a licensed institution rather than at home under Alere nursing care. Alere does not perform toxicology screens in the home. If Alere becomes aware of a maternal addiction during the patient interview, that is made known to the patient's physician if it is not already reflected in the medical record provided by the physician to Alere at the initiation of home care.

The Alere Registered Nurse assesses the patient's environment, completes a psychosocial history, a medication and illicit drug/alcohol/tobacco assessment, a domestic violence assessment, and provides extensive education regarding needs identified in the home. Alere works collaboratively with rehabilitation facilities, physician offices and hospitals to assist the patient with needs associated with addiction as well as any issues identified during the comprehensive assessment.

m. Also under Scope of Services, what services are unique to newborns only?

Alere is able to provide post-partum maternal/newborn assessments. This is not a service which Alere is currently contracted to provide in the state of TN, but it is one that Alere is able to do should the need arise.

n. Please discuss how the applicant intends to develop, manage, implement, supervise and maintain patients' plans of care, including plans to manage patient pain.

Alere works with the physician to develop the patient's plan of care. Alere develops, in consultation with the physician, written orders for home health services which include the specific treatment and modalities to be used and specific amount/frequency and duration. The plan of treatment is reviewed on an ongoing basis as often as the severity of the patient's condition requires. At a minimum of every 62 days, the plan of treatment is sent for physician review and signature.

June 25, 2015

3:30 pm

**FAQ REGARDING PUBLIC CHAPTER 820 (PC 820) AND OTHER REQUIREMENTS
RELATED TO NEONATAL ABSTINENCE SYNDROME (NAS) IN TENNESSEE
(Last Revised June 24, 2014)**

During 2014, the Tennessee General Assembly enacted Public Chapter 820, effective April 24, 2014, which amends T.C.A. § 39-13-107. The new law provides that a woman can be charged with a **misdemeanor** if she illegally uses narcotics during pregnancy and if the baby is harmed as a result (ex. Neonatal Abstinence Syndrome). The intent of PC 820 is to give law enforcement and district attorneys a tool to address **illicit drug use** among pregnant women, through treatment programs including drug courts and particularly in egregious cases such as more than one NAS delivery. PC 820 contains a sunset provision in two years. The state of Tennessee is committed to tracking the impact of the law on mothers and babies. There are several other provisions in law or rule regarding NAS in Tennessee that may cause confusion or uncertainty, particularly among care providers. *The intent of this FAQ is to provide additional clarity to assist with consistency in application of these provisions and to minimize any unintended consequences of misunderstandings of the law or other requirements.*

The following FAQ responses and statements do not supersede the language of the statute, but are merely provided as guidance to health care professionals and other interested parties. The questions and responses are informational in nature and do not constitute legal advice. Moreover, the questions and answers are subject to change. Those who are or may be subject to this law are strongly urged to review the applicable laws and rules and seek their own legal counsel if necessary. The departments impacted by Public Chapter 820 are not bound by this guidance in their interpretation of the law because each situation is unique.

Question: Are health care providers required to notify law enforcement about illegal use of narcotic drugs during a woman's pregnancy that may have caused a newborn to be drug dependent in the context of Public Chapter 820?

Answer: No. The new law (Public Chapter 820) does not require health care providers to report pregnant women or mothers who may be illegally using narcotics to law enforcement.

If a provider "has knowledge of or is called upon to render aid to any child" suffering from abuse or neglect, existing law requires healthcare providers to notify the Department of Children's Services of suspected abuse or neglect of a child. If a report is made to DCS, that department will investigate and determine if law enforcement needs to be involved. You can report at 1-877-237-0004 or online at <https://reportabuse.state.tn.us/>.

Question: What is Neonatal Abstinence Syndrome, or NAS?

Answer: Neonatal Abstinence Syndrome is a condition in which a baby has withdrawal symptoms after being exposed to certain substances in utero. The exposure can involve prescribed and/or illicit drugs. After delivery the baby experiences withdrawal because the substances are no longer being received through the umbilical cord. NAS is a clinical syndrome; the diagnosis typically involves (1) a history of exposure to substances that may precipitate a withdrawal, (2) evidence of the substance in the baby's system and, (3) symptoms consistent with a state of withdrawal. Available literature suggests NAS does not necessarily correlate predictably with the amount or frequency of in utero exposure. Not all cases of exposure will lead to withdrawal syndrome.

June 25, 2015**3:30 pm**

Question: Does Public Chapter 820 change the requirement to report cases of NAS to the Department of Health for public health surveillance?

*Answer: No. The Department of Health made NAS a **reportable condition** as of Jan. 1, 2013. Providers who make the diagnosis of NAS (typically hospitals and birthing centers) should continue to report cases of NAS to the Department of Health.*

Question: Does the Department of Health provide information on the NAS case reports to law enforcement?

Answer: No.

Question: Will mothers automatically be prosecuted if referred to DCS?

Answer: No. Referred NAS cases receive a Child Protective Investigative Team (CPIT) review. The Child Protective Investigative Team determines if the case will be prosecuted. Information regarding Child Protection Investigative Teams and categories and definitions of child abuse and neglect may be found online:

<http://www.tn.gov/youth/dcsguide/policies/chap14/WA1.pdf>

<http://www.tn.gov/youth/dcsguide/policies/chap14/14.6.pdf>

Question: Does Public Chapter 820 change care or medical treatment provided to pregnant women?

Answer: No. This law does not direct any particular medical care or treatment.

Question: Does Public Chapter 820 create criminal liability for providers who prescribe narcotics to women of childbearing age?

Answer: No.

Question: Does Public Chapter 820 prohibit pregnant women from receiving pain management services?

Answer: No. Please refer to the Chronic Pain Guidelines for additional information. They may be found online at <http://health.state.tn.us/Downloads/ChronicPainGuidelines.pdf>.

Question: How does a health care provider identify appropriate substance abuse treatment resources for pregnant women or mothers?

Answer: The health care provider can contact the REDLINE at 1-800-889-9789 24 hours a day, 7 days a week for substance abuse treatment services. Additionally, for treatment for indigent individuals, view the provider list at <http://tn.gov/mental/A&D/DADAS%20Directory.pdf>.

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Question: Are women who take prescribed medications under medical supervision subject to prosecution under Public Chapter 820?

Answer: No. The law specifically states that "prosecution of a woman for assault" may only occur "for the *illegal use* [emphasis added] of a narcotic drug."

Question: Is Public Chapter 820 in effect indefinitely?

Answer: No. The law sunsets in two years.

Question: How does Public Chapter 820 relate to the Safe Harbor Act (2013 Tenn. Pub. Acts, ch. 398) which passed in 2013?

Answer: The Safe Harbor Act deals with services for pregnant women referred for prescription drug use/misuse and the parental rights of pregnant women abusing/misusing drugs.
<http://www.tn.gov/sos/acts/108/pub/pc0398.pdf>

The new law, Public Chapter 820, is a criminal statute concerning the prosecution of women who give birth to infants who are harmed by the women's prenatal drug use and does not specifically deal with a mother's parental rights.
<http://www.tn.gov/sos/acts/108/pub/pc0820.pdf>

Question: Are Public Chapter 820 and the Safe Harbor Act (2013 Tenn. Pub. Acts, ch. 398) contradictory?

Answer: No. Both statutes allow for treatment of pregnant women at risk of delivering a baby with NAS and provide protections from adverse legal consequences. Under Public Chapter 820, "It is an affirmative defense to a prosecution...that the woman actively enrolled in an addiction recovery program before the child is born, remained in the program after delivery, and successfully completed the program, regardless of whether the child was born addicted to or harmed by the narcotic drug."

Question: How can NAS be prevented?

Answer: The primary prevention strategies for NAS include:

- Careful consideration and judicious use of prescribed narcotics in women of childbearing age
- Preventing dependence/addiction in women of childbearing age
- Preventing unintended pregnancies in women using prescribed or illegal narcotics.

Question: What else can health care professionals do to reduce NAS in Tennessee?

Answer:

- Register to use the Controlled Substance Monitoring Database and check it before prescribing an opioid or benzodiazepine. Usage of the CSMD became mandatory April 1, 2013.

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- *Refer to Chronic Pain Guidelines for recommendations on the appropriate treatment of chronic non-malignant pain for women of childbearing age.*
- *Talk with patients who are women of childbearing age about how to prevent an unintended pregnancy.*
- *Screen patients for substance use or risk and refer to mental health treatment resources as appropriate.*
- *Discourage women from smoking during pregnancy; nicotine dependence appears to increase the risk of development of NAS in the baby.*

Question: Where can I learn more about NAS in Tennessee?

Answer: Visit the Department of Health's NAS website at <http://health.tn.gov/mch/nas/>.

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Alere's nurses provide skilled nursing care in the home and offers 24/7/365 support by High Risk obstetrical nurses telephonically in order to answer questions and provide interventional nursing to address the patient's needs.

Reports are provided to the physician weekly and on an as needed basis re: any required change in the patient's plan of care.

Alere works with the physician, patient and OB Pharmacist to manage the patient's pain safely during pregnancy. Alere assesses the patient's pain at every visit and follows up accordingly. Alere does not offer or supervise the provision of pain management pumps.

The Alere Home Care Director ensures supervision and competency of staff by performing ongoing assessment. The Director co-travels to a patient's home to observe a visit to ensure competency annually.

o. From the applicant's experience, please discuss how the proposed service will safeguard against potential medication errors that might possibly result in serious harm (note: this question relates to skilled nursing service involving "medication infusion" and is based on comments found on page 11).

Alere follows policies relative to safely managing infusion pumps. The policies include the requirement to validate all pump programming/dosing with two Registered Nurses prior to patient placement. This is done to ensure the dosage is programmed per the plan of treatment. The pumps are programmed with maximum and minimum dosages as well as lock-out settings that prevent the patient from making changes to the pump that could result in the delivery of the wrong dosage of medication.

p. Please describe how the applicant's governing body monitors and enforces compliance with all patient safety standards of care that apply to the project.

The Tennessee Director reports to the Governing Board and participates in Quarterly review of Policies, Quality and Safety. Alere has an extensive, comprehensive Quality Management program that requires the reporting of all medication errors and all unexpected or adverse events related to patient care and the operation of the Home Care site.

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q. Other than the use of a 24/7 existing Patient Service Center staffed by OB pharmacists and OB registered nurses, are there any additional plans for the use of telemedicine to coordinate patient care activities with physicians and other key parties that participate in the applicant's care model?

There are no such plans at this time. Referring physicians are kept informed of their patients' conditions and the services being provided; but they rely on Alere staff to treat appropriately within the recognized scope of skilled nursing care. This is not a program to create a virtual physician office at the patient bedside. Physicians have no need or time to be present by telemedicine hookups. In the rare event of exceptional needs beyond the scope of appropriate skilled nursing care, the patient is immediately transported to the hospital or the physician office for physician-provided care.

r. If so, what measures will be taken to ensure that the applicant and other parties participating in this service such as pharmacists and patient physicians will comply with the Department of Health's Board of Medical Examiner's Rules (0880-02-.16) for registration & licensing?

For any Tennessee patient, telephonic guidance by Alere OB Pharmacists and OB Nurses at the 24-hour Regional Call Centers is provided only by pharmacists who hold a valid license, and registered nurses who are licensed in the State of Tennessee. These are the only Alere providers serving Alere patients other than the patient's assigned Home Care OB RN.

s. What measures will be taken to comply with patient confidentiality?

All Alere personnel comply with the requirements of the Federal HIPPA rules and regulations, in maintaining patient confidentiality. These are complex and too long to be listed in this response letter. All Alere Home Care employees are required to complete annual HIPAA training and to maintain documentation of all ongoing training and education.

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5. Section C, Need, Item (Project Specific Criteria_

a. Items 5.A and 5.C – It is understood that the applicant is gathering the requested letters from physicians and residents of the proposed 22 counties. However, the applicant should be aware that if the information is not submitted by month end, HSDA's initial review of the application will continue in accordance with the process described in the closing section of this letter below.

The applicant is aware of the value of support letters being provided early in the review process, and appreciates the historic practice of the HSDA in allowing the public to express its support in that way, whenever such expressions become available. The applicant is currently gathering letters and will submit whatever is obtained as soon as obtained.

b. A breakout of patients by services is noted in Table 3. How would patients receiving multiple services be reflected? What projections apply only to newborns in the table? Please clarify.

The Table reflects the primary program recorded for Alere patients. Very few receive care under more than one program; and there is no practical way to identify such patients without a massive survey of medical records.

There are no projections that apply only to newborns. Alere does not currently serve newborns in these areas, but a one-time Postpartum Maternal/Newborn assessment is a service that is offered by Alere and is one that could be contracted for by the Insurance companies should they so choose.

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c. Item 5.A. and 5.B – As noted by the applicant, the comparison cannot be made based on differences between the applicant's bundled charge shown in Table 5.b and the per visit charge of the 5 other agencies shown in Table 5A. However, review of the 2014 provider JAR revealed that charges of the other agencies could be determined on a per patient basis by using the information in Schedules D and E of the 2014 JAR. Please clarify.

SUPPLEMENTAL Table Fifteen-A Revised				
Cost & Skilled Nursing Charges of Agencies Currently in the Service Area				
Agency* FYE 2014	Cost/Visit	Charge/Visit	Charge/Patient	Charge/Hour
1	\$108	\$108	\$3,113	NR
2	\$136	\$136	\$9,517	\$40
3	\$106	\$106	\$8,579	\$44
4	\$NR	\$175	\$2,458	\$55
5	\$97	NR	\$4,030	NR
Alere/Dav'son, CY 2016	NR	NR	\$6,779	NR

Source: 2014 Joint Annual Reports; and Alere management.

***Key to Agencies:**

1. Elk Valley Home Health Care Agency, LLC (76032)
2. Home health Care of Middle Tennessee, LLC (19584)
3. Quality Home Health (25044)
4. Vanderbilt Community and Home Services (19394)
5. NHC Homecare (75024)

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6. Section C, Need Item 3 (Service Area Demographics)

a. The additional 22 counties plus the applicant's existing 14 counties amounts to a total service area of 36 counties. Were the 22 counties identified selected on the basis of public outcry by physicians, legislators, potential patients and family members, hospitals, Department of Health regional and county health departments and other members of the medical community?

Of the above listed groups, insurers and physicians with patients in this area have requested Alere's services. Precise records by county are not kept. Alere estimates receiving two to three calls a month for referrals that cannot be accepted.

However, the HSDA presumably knows that for an established provider, receiving few referral requests for unauthorized counties is not evidence of no area need. Referring physician practices, commercial insurers, and TennCare MCO's become quickly educated after a few phone calls as to which counties Alere can serve. After they learn Alere's territorial limitations, they no longer telephone Alere to attempt referrals for unauthorized counties-even though their patients' only alternative will be to utilize hospitals private physician offices. To call Alere about such a patient would be a waste of their time.

b. Given the majority of new counties that are located in the Upper Cumberland area of Tennessee, what part did geography play in the applicant's decision to add these counties? How will the applicant maintain an active marketing presence in the additional 22 counties given its parent office location in Nashville? Please clarify.

Geography played an important role. Alere is a heavy TennCare provider. TennCare MCO's are Statewide. It is efficient for Alere's Davidson County agency to seek regionwide licensure in one Certificate of Need in order to be available to MCOs and physician practices, wherever their patients reside. Piecemeal application based on county-by-county service requests would be an inefficient and very costly exercise.

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7. Section C, Need Item 5 and 6 (Historical and Projected Utilization)

Historical Utilization of Existing Providers - in this and other parts of the application that address the target population, the applicant's research and analysis significantly helps quantify the number of females that comprise caseloads of the existing 72 home health agencies in the proposed 22 counties. For example, Table 10-C shows that women in the age 18-64 age bracket who received home care for any condition by the 72 agencies serving the 22 counties totaled only 12.9% of 18,364 total patients in 2014, with 59 of the 72 agencies averaging 20% or less. This analysis appears to point to 13 agencies that may be serving the target population.

a. Please identify the 13 agencies, describe the skilled nursing & related services that the 13 agencies provide to high risk OB patients and newborns, and provide their utilization for the 201-2014 period. As a suggestion, direct contact with the agencies may be one way to validate the assumptions and analysis provided in the application.

The 13 agencies identified in your question are the first 13 listed in the table below, along with the number of female patients age 18-64 that each served in 2014 within the proposed 22-county service area, and the percent that represented of their total patients in the service area. Only five of those agencies served more than 9 female patients age 18-64 in all 22 area counties last year. Their full 2012-14 utilization in all their authorized counties is in Table Eight of the application, pages 42e-f.

To enlarge the sample, the applicant added to the table 5 more agencies that (a) had 15% or greater dependence on service area females 18-64 years of age AND (b) served at least an average of one female per service area county in 2014 (i.e., 22 or more female patients). This added some higher-female-volume agencies to the sample.

Alere staff telephoned each agency to determine if it serves high-risk pregnant women, using key questions as to skills or scope of care. None of the agencies on the lists provides these services to high-risk pregnant women.

Alere feels that this sample of 18 agencies with higher-than-average services to women, or to this area's women, strongly suggests that the area's high-risk pregnant women need Alere's services.

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Alere also feels that even if another provider comes forward with evidence of providing Alere's type of service, nevertheless area consumers, physicians, and insurers have a strong interest in having a meaningful choice (i.e., reasonable duplication) among agencies for patients who require high-risk specialized care.

Without that, providers will never have to engage in healthy competition for optimal quality of care and optimal outcomes. The applicant believes that the HSDA Board will want to strike a balance between creating such beneficial consumer/insurer choices, and avoiding excessive duplication of ordinary home care services.

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State ID Number	Agency Name and Information Provided To Alere OB RN Making Telephone Inquiry	Estimated 2014 Female Patients 18-64 Yrs, from Alere's Proposed Counties	Females Age 18-64 as Percent of Agency's Patients Within Alere's Proposed Counties
40075	Henry County Med Center Home Health – Paris – Spoke with Becky Allen who stated “We don’t do pregnancy”.	1	50% of 2
02024	Heritage Home Health – Shelbyville – Spoke with Candy who stated that their agency does not do OB or Pediatrics	3	50% of 6
94084	Vanderbilt HC Affil w/Walgreens IV & RT Svcs – Brentwood – Do not have OB nurses available to see patients, they only do infusion.	4.5	45% of 10
63044	Suncrest Home Health of Nashville, Inc.- Clarksville – They do not provide obstetrical services, have no OB nurses on staff and don’t have the ability to do fetal assessment.	11.5	31.9% of 36
19364	Intrepid USA Healthcare Services – Nashville – They do not have nurses to manage pregnancy. They do primarily wound care and rehabilitative services. They do not participate in TENNCare	1.5	30% of 5
19714	Angel Private Duty and Home Health, Inc. (Friendship) – Nashville – Per Bianca, no nurses on staff that manage pregnancy	2.5	25% of 10
09065	Baptist Memorial Home Care & Hospice – Huntingdon – per Crystal, no maternal fetal nurses and they do not provide those services in the home.	1.5	25% of 6
19734	Coram CVS Specialty Infusion Svcs – Nashville – Per Robin, they are an Infusion Pharmacy only, not a Home Health Agency, no OB Home Care Nurses.	0.5	25% of 2
19494	Elk Valley Health Services Inc – Nashville – they do provide specialized home care, but do not provide care to pregnant patients.	12.5	24.5% of 51
27085	Volunteer Home Care, Inc – Humboldt- spoke initially to Lisa who transferred me to Nicole. Nicole stated that they do not have any nurses on staff that specialize in OB, nor do they have the equipment to do Fetal Heart Tone assessment.	12.5	23.6% of 53

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36025	Deaconess Homecare (Gericare) – Savannah – Per Karen, “We don’t do pregnancy care, we don’t have pregnancy nurses. We don’t have the ability to listen to the baby”.	4	21.9% of 183
60044	Maury Regional Home Services – Columbia – Per Tracy/Dania, No Pregnancy Nurses, no ability to manage pregnant patients. Dania states that she has been in home care for 20 years and does not know of anyone who can provide service to high risk pregnant patients.	74.5	21.3% of 350
19584	Home Health Care of Middle TN – Nashville – Spoke with Amanda, they don’t have nurses who specialize in pregnancy and don’t have the ability to listen to Fetal Heart Tones	6.5	21% of 31
95034	Deaconess Homecare (Cedar Creek) Mt. Juliet Per Debbie, they don’t have the ability to care for Obstetric patients	117	19.6% of 597
52054	Deaconess Homecare (Elk Valley)- Fayetteville Per Lisa, no skilled pregnancy nurses, they do not take TennCare patients.	131.5	16.9% of 778
25044	Quality Home Health, Jamestown; Melinda states that they do not staff nurses that are skilled to manage pregnancy conditions, no ability to listed to Fetal Heart Tones	267.5	15.7% of 1704
19324	Suncrest Home Health, Madison; Per Tabitha, they do not offer pregnancy service, no dopplers to listen to fetal heart tones. Gave me the number of their private duty arm of the business, spoke with Danielle who states that they are not equipped to manage complications of pregnancy and that they do not have OB nurses on staff.	53	16.7% of 318
25034	Quality Private Duty Care, Jamestown; Wilma informed me that they don’t have Obstetric Nurses on staff, do not manage pregnancy, cannot listen to Fetal Heart Tones.	131	18.6% of 705

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SUPPLEMENTAL BASE TABLE 1: 2014 Agency Dependence on Alere's 22 Proposed Counties

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SUPPLEMENTAL BASE TABLE 1: 2014 Agency Dependence on Alere's 22 Proposed Counties

TDH ID	AGENCY NAME	Total Agency Patients in TN	Total Agency Patients From Alere's Proposed Counties	Patients Served by Agency in Each of Alere's 22 Proposed Counties																				Percent of Agency Dependence on Patients in Alere's Proposed Counties	Agency Total Patients Age 18-64 in Alere's Proposed Counties	Agency's Female Patients Age 18-64 in Alere's Proposed Counties (Estimated @ 50% to 1 Decimal Place)	REVISED TITLE
				Clay	Cannon	Greene	Franklin	Madison	Warren	Madison	Franklin	Warren	Madison	Franklin	Warren	Madison	Franklin	Warren	Madison	Franklin	Warren	Madison	Franklin	Warren			
71084	Intrepid USA Healthcare Services	281	281	30	1	11																		100.0%	53	26.5	9.4%
89064	Intrepid USA Healthcare Services	804	55	21		13																		99.1%	65	32.5	9.7%
52044	Lincoln Medical Home Health & Hospice	339	339																					22.5%	149	74.5	21.3%
52044	Maury Regional Home Health	1,553	350																					0.0%	0	0.0	0.0%
33253	Memorial Hospital Home Health	2,651	0																					0.0%	0	0.0	0.0%
33253	NHC Homecare	411	0																					49.7%	305	152.5	11.8%
60074	NHC Homecare	2,591	1,299																					0.0%	0	0.0	0.0%
74094	NHC Homecare	1,842	0																					33.6%	312	156.0	11.1%
75024	NHC Homecare	4,180	1,408																					65.2%	197	98.5	14.8%
82084	Quality First Home Care	1,023	667																					47.5%	535	267.5	15.7%
25044	Quality Home Health	3,591	1,704																					78.9%	262	131.0	18.6%
25034	Quality Private Duty Care	884	705																					0.0%	0	0.0	0.0%
39035	Regional Home Care - Lexington	582	0																					15.1%	7	3.5	7.4%
41034	St. Thomas Home Health (Hickman Co. HI)	311	47																					12.2%	92	46.0	17.6%
16034	Suncrest Home Health	2,122	258																					6.9%	106	53.0	16.7%
19324	Suncrest Home Health	4,624	318																					56.2%	352	181.0	13.0%
33044	Suncrest Home Health of Nashville, Inc.	2,465	1,396																					2.8%	23	11.5	11.5%
33024	Suncrest Home Health of Nashville, Inc.	1,276	36																					24.5%	66	33.0	11.5%
33025	Tennessee Quality Homecare - Southwest	988	116																					11.7%	22	11.0	9.5%
30045	Tennessee Quality Homecare - Southwest	751	0																					0.0%	0	0.0	0.0%
32122	Univ. of TN Med. Ctr Home Health (Morristown)	1,700	0																					7.4%	9	4.5	45.0%
19394	Vanderbilt Community & Home Services	135	10																					1.8%	25	12.5	23.6%
54084	Vanderbilt Home Care, Inc.	2,995	53																					8.1%	29	14.5	16.7%
27085	Volunteer Home Care, Inc.	1,797	146																					0.7%	3	1.5	12.9%
20055	Volunteer Homecare of West Tennessee	1,283	9																					18.2%	4,733	2,366.5	
19694	Willowbrook Home Health Care Agency	100,882	18,364	543	256	1,404	673	998	1,510	1,015	715	426	1,753	423	1,224	940	85	845	261	2,625	626	367	349	1,032			

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Applicant's Historical and Projected Utilization- Please address the following items:

- b. Utilization by newborns does not appear to be included in Table 11.A and 12.B. Please clarify.**

Alere does not currently serve newborns in these areas, but a one-time Postpartum Maternal/Newborn assessment is a service that is offered by Alere and is one that could be contracted for by the Insurance companies should they so choose.

- c. Contractual adjustments from charges amounts to approximately 60% of gross operating revenue. It seems that the applicant's high TennCare mix (71% average) may be the primary factor that accounts for the large amounts provided for contractual adjustments in Year 1 and Year 2. Please clarify by describing how TennCare reimburses for the applicant's services.**

- d. Net Operating Revenue in the Historical Data Chart and the Projected Data Chart**

(current and proposed counties chart version) differs from the amounts shown in Table 16 on page 56 (payor mix profile table). Please clarify.

- e. Using the staffing plan shown in Table 18 on page 60, the \$45,373 allocated in Year 1 for salaries and wages expense (Line D.1) for the additional 4.8 FTE per diem nursing staff for the 22 counties appears to be understated. Please clarify.**

- f. Please clarify why the \$1,786,408 gross operating revenue in the Historical Data Chart (\$8,932/patient) differs from the \$1,706,408 (\$8,532/patient) in Table 14 on page 53.**

Questions 7c through 7f above must be answered by an Alere financial officer who has been out of town and unavailable since the supplemental questions were received last Friday. She is returning soon and Alere will respond to these questions under separate cover.

8. Section C, Economic Feasibility Item 2 and Item 4

- a. The funding letter from a management representative of United Health Group, LLC was omitted from the attachments.**

That letter is attached following this page.

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b. Review of the Consolidated Balance Sheets for the parent company revealed an excess of current liabilities over current assets for the 2013, 2014 and 2015 fiscal year periods such that the company's current ratio may be below industry norm. Although it is understood that the capital costs of the proposal are primarily consulting fees and are minimal, is sufficient cash from cash reserves available to support the project in light of United Health Group's current obligations (such as accounts payable) as identified in current liabilities?

9. Section C. Economic Feasibility Item 5 (Average Gross Charges)

The response with charts is noted.

What accounts for the decrease from the average gross charge of \$8,930 in the Historical Data Chart in 2014 to the average gross charge of approximately \$6,787 per patient in Year 1 that is shown in Table 13B? Please clarify.

10. Section C, Economic Feasibility, Item 9

The projected payor mix information in Table 16 on page 56 of the application is noted.

a. As noted in an earlier question, the amounts for Net Revenue for 2014, Year 1 and Year 2 differ from the Historical and Projected Data Charts. Please explain.

Questions 8b, 9, and 10a above must be answered by an Alere financial officer who has been out of town and unavailable since the supplemental questions were received last Friday. She is returning soon and Alere will respond to these questions as quickly as possible under separate cover.

b. Please identify the commercial payor plans that reimburse for the applicant's high risk obstetrical patient and newborn home health services with specific note as to the applicant's contracted commercial plans that would apply to potential patients in the proposed 22 county expansion of the applicant's service area. In your response, please briefly describe the reimbursement methodology used by same, noting any key differences between the commercial and TennCare MCO plans.

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Commercial Payor Plans include Aetna, Cigna, Humana, and United Health Care. The reimbursement from these agencies utilizes the same bundled methodology as in Alere's TennCare MCO plans. Each insurance plan is contracted with as a single entity, and the rates are set forth in individualized contracts with each plan. Those are proprietary methodologies, negotiations, and rates, just as they are for hospitals that negotiate with payers for managed care pricing.

11. Proof of Publication

Although referenced in the application, publisher's affidavits or copies of the LOI in newspaper article with date and mast intact was omitted from the application.


a. Please provide this information to confirm publication of the LOI on June 10, 2015 in all 13 of the newspapers identified in the list that HSDA received on June 10, 2015 with the LOI.

b. In your response, please complete the table below showing the status of publication of the LOI in a newspaper of general circulation in each of the 22 counties in the CON application in accordance with state law.

Proofs of publication in all required newspapers are attached at the end of this response letter, including the table requested in 11b.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn
Consultant

June 25, 2015**3:30 pm****Norman S. Ryan, M.D.**

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 Wilmette, Illinois 60091
 (847) 906-4046 (home)
 (312) 620-2096 (office)

Norman.ryan@alere.com nsryan@sbcglobal.net norman_ryan@rush.edu

Professional Experience**Alere Health**

2013-present **Senior Vice President, Health Intelligence and Chief Medical Officer, Quality Alere Health**
(Subsidiary of Alere, Inc., Waltham, Massachusetts)

- Raised effectiveness of health intelligence in areas of technical innovation, product development, clinical effectiveness, financial analysis related to performance guarantees and cross-functional team development
- Executive Transition team member for recent divestiture of Alere Health (Alere, Inc. subsidiary) during multiple negotiations, presentations with both financial and strategic potential purchasers
- Performed research and analysis to demonstrate value of Alere Health programs
- Designed, organized and provided analytics support to Alere Health pilot programs enhancing clinical effectiveness
- Participated in and directed development of predictive modeling for vulnerable populations
- Supported clinical direction in diverse clinical programs
- Key point of contact for industry consultants
- Oversaw quality initiatives throughout the organization as an executive function in Alere Health; Chair Quality Improvement Committee
- Supported and participated in research studies for publication
- Participated in strategic alliances related to analytics and reporting
- Participated in industry thought leadership initiatives on population health management effectiveness measurement and reporting (PHA, HERO, other)
- Book of business outcomes analysis

Rush University Medical Center

2010 - 2013 **Senior Medical Director, Rush Health (Physician Hospital Organization for Rush University Medical Center, Chicago)**

- Practicing Family Physician/Geriatrician
- Rush University Medical Center College of Medicine Faculty
- Awarded Rush Excellence in Clinical Service award 2012 for work on development of Medical Homes at Rush. Inter-professional team achieved 2011 NCQA level III Medical

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Home recognition for 7 practices at Rush. Participated in development of 43,000 patient registry, enhancements to Epic EMR to accommodate new data collection models, cross departmental integration for coordination of care, new reporting of results and outcomes, cooperation with multiple professionals to participate in effort as well as application and interaction with NCQA.

- Member Rush University hospital readmission taskforce
- Lead on multiple integrated health system clinical performance committees
- Team development of clinical decision support modules in Epic electronic medical record
- Accountable care organization (ACO) development taskforce
- Member Advisory Board University of Illinois Roybal Center for Health Promotion and Behavior Change

2006-2010

- Assistant Professor Family Medicine
- Practicing Family Physician/Geriatrician
- Instructor Physical Diagnosis
- Supervisor homeless shelter medical clinic
- Member advisory board, State of Illinois Department on Aging long-term care
- Advisor/mentor for award winning team Kellogg School of Business/Northwestern Medical School/Chest Foundation Disparities in Asthma Care case competition
- Member Advisory Board UIC Roybal Center for Health Promotion and Behavior Change
- Member Advisory Board UIC CDC sponsored Worksite Wellness Project

United Healthcare**2003-2006**

National Medical Director, Medical Management Programs, United Healthcare Clinical Operations

Responsible for the clinical development and implementation of United Healthcare (UHC) medical management programs throughout the United States in such areas as onsite nursing and case management. In addition, responsibility for clinical integration of newly-acquired companies and the oversight of clinical programs developed for and purchased by United Healthcare

- Onsite Hospital Assessment Program: To help expedite in-patient care as well as the transitions to outpatient settings, organized project concept, developed and implemented national onsite program for medical personnel in target hospitals. Managed 35% inpatient hospital utilization in the U.S. for United Healthcare in key, highest volume hospitals throughout the country with positive measured pre/post case-mix adjusted results for length of stay and quality
- Spectrum program: Developed low-touch, high-volume telephonic case management program, "Spectrum", in KY and FL test markets. Using only evidenced-based interventions, developed connections between at-risk participants and the medical system to improve measured outcomes in selected disease areas. Focus on congestive heart failure, coronary artery disease, diabetes. Using case-mix, risk-adjusted methodology demonstrated results of total intervention and subgroup performance.
- Vendor oversight - SPECKSS: Developed framework for consistent, required, enterprise-wide evaluation of clinical outreach programs using overview criteria for evaluation at

June 25, 2015**3:30 pm**

system level: Total size of target population; modifiable percentage of population; engaged percentage of population; enrolled percentage of population; "key value levers" which if modified predict positive change, improvements in clinical outcomes and costs; and improvement validation through identified data sources/ control groups. For each criteria a set of evidence was required to demonstrate validity of statements.

- Community Acquired Pneumonia multifaceted national project focused on Respiratory syncytial virus infection (RSV) prevention, Community Acquired Pneumonia guideline awareness, influenza and pneumovax immunizations

2003

Divisional Medical Director Medical Expense Management, Clinical Operations North Division. Remained part-time in CMO role, Illinois until June 03. Member President's Leadership Development Program

- Oversaw development and implementation of all Medical Expense Management activities for the North Division
- Matrixed responsibility for performance management of Medical Directors in the Northern United States for medical expense management activities
- Led project to attenuate hospital utilization trend in UHC. Spearheaded inter-segment project to align efforts and develop cooperation between sister companies, Care Management and Ingenix, with United Healthcare
- Developed hospital utilization targets for each UHC market through negotiation with associated partners in markets, Care Management and Ingenix
- Headed team development of authorization-based hospital utilization early warning reporting tool for management of hospital days (Bellwether report)
- Participated with Ingenix in development of claims-based hospital utilization reporting tool for the market level
- Developed with team the hospital data sharing "HDS" approach and tools.
- Implemented hospital data sharing nationally
- Developed multifaceted national project for community-acquired pneumonia with educational and public sector involvement in addition to the more traditional datasharing activities and best practice dissemination. Managed multiple funding streams in collaboration with Ingenix
- Developed national rapid response project for arthroscopy following New England Journal of Medicine article describing new evidence of best practice in this area.
- Participated in early development of employer data sharing (Lanco-Chicago based company)
- Member President's Leadership Development Program for valuable top talent management employees in United Healthcare

2001

Chief Medical Officer and Vice President, United Healthcare Illinois
responsible for medical services in 1 million member health plan in Illinois.

1999

Vice President Health Services, United Healthcare, Illinois

Medical head of 1,000,000 member mixed-model managed care plan in Illinois during turnaround. Responsibilities for all medical management related activities. Head of Government Sales department. Responsible for medical aspects of turnaround of troubled company with multi-year history of losses in both finances and reputation

- Reduced excess hospital admission rates using both collegial-collaborative methods and

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- high technology predictive modeling
- Hired new team of directors, medical directors, project managers
- Upgraded reputation of reputation-challenged company in physician community
- Rebuilt Clinical Advisory Committee to give advice to our company from broad range of sources including academic, group practice, solo practice, organized medicine
- Participated in Illinois State Medical Society including appointment to Council on Economics to stay in tune with needs and viewpoints of medical community which has conflicted relationship with managed care
- Spearheaded with team the cultural change to "Care Coordination" philosophy internally, eliminating utilization management approach
- For first time in company history achieved JCAHO accreditation with exceptionally high scores in local and site surveys. Full three year accreditation .
- Reconfigured quality management team and approach toward "active quality management"
- Headed Medicare network reconfiguration project as Head of Government Sales
- Made university connections for future research, with original proposals now in place
- Continued in medical practice on part-time basis, incorporating medical student and resident education activities
- Presented to CDC national conference on chronic care, participated in review of world literature on exercise in the elderly and continued to shepherd development and expansion of SHAPE, the Senior Health Alliance Promoting Exercise, in Chicago to improve the health of our community

Humana Health Care Plans, Illinois

1997- 1999

Market Medical Director

Responsible for medical management in approximately 750,000 member health plans in Illinois and northwest Indiana with POS, ASO, HMO, PPO and specialty lines of business. Lead through ongoing challenges to remain largest and first or second most profitable plan in Humana nationally. Managed through sale and divestiture of 220,000 member group medical practice, which had been an integral part of health plan from its inception

1993-1997

Medical Director, Network Management

Medical Director responsible at several levels for approximately 650,000 members in direct contract IPA-model, Point of Service, ASO contracts, PPO, as well as Staff Model and Affiliated Medical Groups of Staff Model. Assisted in expansion of this network from 60,000 in 1993 to 650,000 in 1997

Member of senior management of one of the largest multi-specialty medical group practices in the United States with 220,000 members and 220 employed physicians

Overall responsibility for direction and strategic planning of all Utilization Management activities in both Staff Model and contracted IPA-model managed care plans. Responsible for quality management, relationship management and involvement in strategic planning, network development, credentialing and contracting in the contracted network

Rush Health Plans

1993

Acting Medical Director

130,000 member mixed-model Health Plan in Chicago

1990-1993

Associate Medical Director for Utilization Management

Overall responsibility for utilization of medical resources for the Rush Anchor HMO. Supervised department of 50 Utilization Management employees in 21 offices in Illinois and Indiana. Effected utilization of resources through consistent and directed cultural change in the medical practice of both employed physicians and network of consultant specialists

- Established and implemented policies which reduced non-Medicare hospital days utilization by 12%, yielding millions in decreased yearly hospital costs
- Supervised team of physicians managing care of patients from branch offices hospitalized at Rush-Presbyterian-St. Luke's Medical Center; improved efficiency of tertiary care and communication with network physicians. (Early "hospitalists")
- Directed development of comprehensive office and specialty-specific consultant directory prioritized by desirability of contract. Implemented use of directory in managing referrals within contracted network
- Authored organ transplant policy
- Originated, edited and published newsletter of clinical activities, incorporating Utilization Management, Quality Management and Pharmacy control data, in order to facilitate information dispersal throughout regional network

1990

Director of Quality Management Interim Director of Utilization Management

Conducted case review and risk management activities. Promoted health maintenance protocols and policies in addition to directing Utilization Management department

Professional Activities

United Healthcare

- National Clinical Operations leadership team, United Healthcare, National Medical Director Medical Management Programs
- Key management North Division United Healthcare
- Senior Management, United Healthcare, Illinois
- Chairman, Medical Commission, Illinois Association of Health Plans
- Appointee to Governor's commission on Credentialing for State of Illinois
- Illinois State Medical Society Council on Economics
- Member of SIP13 Advisory Board, researching world literature on exercise in elderly under CDC/NIH grant
- Key participant in and founding member of SHAPE Senior Health Alliance Promoting Exercise Public/private coalition to promote health in Chicago area seniors
- Elected Member of the Institute of Medicine of Chicago, 2001
- Kickoff speaker and founding participant Antibiotic Education Council of Illinois October 2002

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- Member of United Healthcare President's Leadership Development Program 2003
- Overall oversight internal and external disease management vendors, including chf, neonatology, diabetes, asthma
- Worked closely with companies developing predictive modeling using artificial intelligence to determine likely persons to fall into high risk medical categories over time (Landacorp)
- Organized north division clinical analytics team

1993-1999 **Humana**

- Senior Management, Humana Health Plans, Inc., Chicago Market
- NCQA steering committee for Chicago Market – successful full, three year accreditations twice
- Chair Clinical Quality Committee, Co-Chair Quality Council, Humana
- Chair, Market Utilization Management Committee, Humana Health Plans
- National Policy Committee, Humana, Inc., Corporate Office
- Corporate Technology Assessment Taskforce, Humana Health Plans, Inc.
- Corporate Management Reporting Taskforce, Humana Health Plans, Inc.
- Corporate Chronic Care Case Management Advisory Panel
- Corporate Disease Management Company Assessment and Implementation team/National Steering Committee. Oversight and evaluation of programs for CHF, Diabetes, Neonatology, Rare diseases, Coronary Artery Disease, Asthma, COPD
- Developed and implemented CHF disease management program in Chicago Market. Developed effectiveness comparisons with national programs
- Developed and implemented influenza and pneumonia immunization programs in both multi-specialty group practice and extended contracted physician Market network
- Working with teams, formulated approaches to measurement of surrogate indicators of health status decline: e.g. ER visits, hospital readmissions and developed programs to mitigate these declines
- Developed data and interrelated data trend analyses to monitor engaged populations for under-utilization of medical services.
- Chief Medical Editor Humana Corporate National Provider Newsletters
- National Humana Pharmacy and Therapeutics Committee
- Chairman, Illinois Association of HMOs Medical Commission
- Coordinated and managed 15 physician "hospitalist" program (until June 1998) at nine hospitals involving care of 180,000 patients - thought to be largest in U.S. at the time.
- Part-time clinical practice incorporating medical student and resident teaching
- Seminar with Heero Hacquebord (Dr Deming Partner) on statistical process control

1990-1993 **Rush Health Plans**

- Chair Member Services Committee which makes benefits policy decisions
- Chair Medical Advisory Committee which makes new technology policy decisions
- Co-chair of coordination team for joint primary care and subspecialty taskforces at Rush-Presbyterian-St. Luke's Medical Center to develop "critical paths" for management of specific clinical problems
- Professional Advisory Committee, Board of Trustees, Rush-Presbyterian-St. Luke's Health Plans, Inc. Advised the Board of Trustees on professional activities occurring in the Rush Health Plans, particularly those involving Quality Management and Utilization Management.
- Medical Advisory Board, Chartwell Midwest Home Infusion Services—a joint corporation with Tufts, New England Medical Center, Massachusetts General Hospital and Rush-Presbyterian-St. Luke's Medical Center. Provided medical oversight on policies and procedures used in home and clinic infusion services

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- Developed onsite physician rounding program at Rush for patients admitted from outlying Anchor offices
- Analyzed and developed activities toward reducing Medicare hospital readmission rates
- Expanded medical communication with publication of Clinical Newsletter to multispecialty group practice
- Early emphasis on "outcomes research", "clinical approach validity"—precursors of "evidence based medicine"
- Part-time clinical practice, Rush Anchor Multi-specialty Medical Group Practice

1986-1990 **Rush Health Plans**

- President, Medical Staff, Rush Anchor, 120 physician, multi-specialty group medical practice
- Member Board of Trustees, Rush-Presbyterian St. Luke's Health Plans
- Finance Committee, Rush-Presbyterian St. Luke's Health Plans Board of Trustees
- Corporate Oversight Committee on Credentials, Rush-Presbyterian St. Luke's Health Plans

As Medical Staff President participated in managed care administration as a member of the Executive Committee, attended regular administrative meetings of the line administration and was an active member of the Board of Trustees and committees of the Board

1984-1986 Secretary, Rush Anchor Medical Staff

Professional Associations

American Academy of Family Physicians
 Illinois Academy of Family Physicians
 Illinois Academy of Family Physician Foundation Board Member
 Illinois State Medical Society (Council on Economics)
 Illinois Association of Health Plans (Chair, Medical Commission)
 American Geriatrics Society
 American College of Physician Executives
 Institute of Medicine of Chicago
 Chicago Asthma Consortium (Advisor to Board)

Certification

Certified by the American Board of Family Medicine, October 1982, Recertified 2002, Recertified 2009
 Certificate of Added Qualification in Geriatric Medicine 1988, 1998
 Licensed Physician, Illinois 1978
 Licensed Physician, Colorado 1983

Post-Graduate Training

1980-1982	Resident, Rush Presbyterian St. Luke's Medical Center - Christ Hospital Family Practice Program, Chicago, Illinois
1977-1978	Resident, Flexible Program, Illinois Masonic Medical Center, Chicago, Illinois
7/75 to 10/75	Clerkship, State University of New York at Buffalo, New York
8/76 to 3/77	Clerkship, State University of New York at Buffalo, New York

June 25, 2015**3:30 pm****Medical Practice Experience**

1998-present Rush University Medical Center
 1993-1998 Humana Health Care Plans, Evanston office
 1982-1993 Rush-Presbyterian-St. Luke's Medical Center, Rush Anchor 120 physician multi-specialty group medical practice
 1978-1980 General Practice, DeKalb, Illinois
 Northern Illinois University
 Men's Intercollegiate Sports Physician, Northern Illinois University

Teaching Appointments

1986-Present Assistant Professor, Rush Medical College, Chicago, Illinois
 1982-1986 Instructor, Rush Medical College, Chicago, Illinois
 1969-1970 Teaching fellow, Washington University, St. Louis, Missouri

Education (Medical)

1970-1976 Medizinische Universität Graz, (University of Graz Medical School), Graz, Austria - M.D.
 1969-1970 Washington University, St. Louis, Missouri, Graduate work in Developmental Biology
 1965-1969 University of Illinois, Champaign, Illinois, Bachelor of Arts, Biology

Education (Business)

2002-3 Wharton School of Business, University of Pennsylvania, Executive Education Program
 1999 Harvard School of Public Health, Executive Education Program Health Care Strategy
 1997 Kellogg School of Business, Northwestern University, Executive Education Program
 1994 NCQA Quality Improvement Systems Training. Boston, Mass.
 1993 Kellogg School of Business, Northwestern University, Executive Education Program
 1990-1994 American College of Physician Executives, PIM I, II and III (Medical Management)
 1997 Emerging Role of Hospitalists, Goldman/Wachter, University of California San Francisco

Some Presentations, Publications and Media:

2010 McGraw Hill Family Medicine Board Review Fourth Edition Editor, Chapter One: Cardiovascular

Rush Health 7th Annual Employer Symposium "Health Management Connectivity" Keynote speaker.
 Rush University Medical Center, Chicago. 2010

CBS.com--EXPERIMENTAL TREATMENTS

TV appearance: Presented the managed care perspective on decision-making for coverage of experimental treatments. At CBS affiliate Chicago, Illinois, 10 p.m. news

ABC <http://www.healthsurfing.com/health/2000/02/07/>

TV appearance: "Managing Managed Care : The debate over HMOs" produced by Sandy Krawitz, reported by Lucky Severson, story by Shawn O'Leary - "Health Surfing" July 2, 2000

Chicago Public Radio WBEZ <http://www.wbez.org/frames.asp?HeaderURL=lv12hd.htm&BodyURL=search%5Cquery.asp>

Do insurance companies have a double standard? Eight Forty-Eight's Victoria Lautman talks with Illinois State Representative Mary Flowers and Dr. Norman Ryan, Chairman, Medical Directors Commission for the Illinois Association of Health Plans, about the lack of health insurance coverage for contraceptives August 12, 1999

PBS Fred Friendly Seminars, National Outreach Program, Bill Kurtis, Moderator
 "Who Cares: Chronic Illness in America." Panel discussion, 10/24/01

Centers for Disease Control, Atlanta, 16th Annual Chronic Disease Conference, Presentation: "Successful Strategies in the Dissemination and Diffusion of Health Promotion" 2/27/02

Kellogg School of Management, Northwestern University, Evanston, Illinois Seminar: "Managed Care Strategy" 7/30/03

Kellogg School of Management, Northwestern University, Evanston, Illinois Seminar: "Managed Care Strategy" 7/29/04

University of Illinois School of Public Health. Annual Lecture in Long-Term Care policy course: "Managed Medicare Principles" 1998 forward to date

Kellogg School of Business/Chest Foundation Case Competition Award winning team. May 2008
 OpenMic.Health: YouTube type videos about asthma real-life experiences created by young people in community for presentation in health clinic waiting rooms. Using "viral marketing" to spread positive asthma messages through target audiences. Interspersed with public health announcements, community service announcements, select advertising and packaged entertainment

Mentored/Advised team of graduate students from Northwestern Business and Medical Schools in development of sustainable business plan for company with *creative organizational model to provide the informational and behavioral assistance required to substantially increase the identification, education, prevention, and treatment of asthma among underserved populations in Chicago.*

June 25, 2015**3:30 pm****11. Proof of Publication**

Although referenced in the application, publisher's affidavits or copies of the LOI in newspaper article with date and mast intact was omitted from the application.

a. Please provide this information to confirm publication of the LOI on June 10, 2015 in all 13 of the newspapers identified in the list that HSDA received on June 10, 2015 with the LOI.

b. In your response, please complete the table below showing the status of publication of the LOI in a newspaper of general circulation in each of the 22 counties in the CON application in accordance with state law.

County	Name of Newspaper of General Circulation	Address	Date LOI Published	How often is this Newspaper Distributed?
Cannon	Cannon Courier	210 West Water Street, Woodbury, TN 37190	June 10, 2015	Weekly
	Southern Standard	105 College St., McMinnville, TN 37110	June 10, 2015	Three days per week
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Clay	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Cumberland	Crossville Chronicle	125 West Ave. Crossville, TN 38555	June 10, 2015	Three days per week
DeKalb	Southern Standard	105 College St., McMinnville, TN 37110	June 10, 2015	Three days per week
	Smithville Review	106 South First Street Smithville, TN 37166	June 10, 2015	Weekly
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Fentress	Fentress Courier	P.O. Box 1198 Jamestown, TN 38556	June 10, 2015	Weekly
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Franklin	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Giles	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Humphreys	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Jackson	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily

Lawrence	Lawrence County Advocate	121 North Military Street, Lawrenceburg, TN 38464	June 10, 2015	Daily
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Lewis	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Lincoln	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Macon	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Moore	Moore County News	P.O. Box 500 30 Hiles Street Lynchburg, TN 37352	June 10, 2015	Weekly
Overton	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Pickett	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Putnam	Herald-Citizen	1300 Neal Street Cookeville, TN 38501	June 10, 2015	Sunday-Friday
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Smith	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Stewart	Leaf-Chronicle	200 Commerce Street, Clarksville, TN 37040	June 10, 2015	Daily
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Trousdale	Hartsville Vidette	206 River St. Hartsville, TN 37074	June 10, 2015	Weekly
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
Van Buren	Southern Standard	105 College St., McMinnville, TN 37110	June 10, 2015	Three days per week
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily
White	Southern Standard	105 College St., McMinnville, TN 37110	June 10, 2015	Three days per week
	Tennessean	1100 Broadway, Nashville, TN 37203	June 10, 2015	Daily

The following counties border certain counties in the CON application:

Dickson	Dickson Herald	104 Church St. Dickson, TN 37055	June 10, 2015	Bi-weekly
Maury	Columbia Daily Herald	1115 South Main Street, Columbia, TN 38401	June 10, 2015	Sunday-Friday
Rutherford	Daily News Journal	224 North Walnut Street, Murfreesboro, TN 37130	June 10, 2015	Daily

July 16, 2015

Jeff Grimm, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1506-025
Alere Women's and Children's Health

Dear Mr. Grimm:

This letter responds to the questions remaining in your first request for supplemental information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

3. Section A, Applicant Profile, Item 12

HSDA staff is aware that home health agencies in Tennessee need Medicare certification in order to participate in TennCare MCOs. However, the comments indicate that Medicare certification is not necessary for the reasons provided. With a TennCare payor mix of approximately 48% or higher, what sort of exemption or waiver did the applicant receive from TennCare in this regard?

No exemption or waiver from TennCare was necessary for Alere because the TennCare regulations requiring participation in Medicare in order to obtain reimbursement from TennCare do not apply to Alere.

As explained in the application, Alere does not meet the requirements for a Medicare provider number. This results from the fact that Alere treats young, pregnant women exclusively and does not consistently maintain the minimum average patient census needed to participate in Medicare. The lack of a Medicare provider number, however, does not limit Alere's ability to work with the TennCare MCOs.

Unlike all (or virtually all) other home health providers in Tennessee, Alere is not paid using either the TennCare or Medicare fee schedules. Indeed, most of the highly specialized services provided by Alere are not covered by either the TennCare or Medicare fee schedules. Nonetheless, the TennCare MCOs want to make these services available to their members due to the demonstrated health benefits and the significant cost savings that Alere's services make possible through sharply reduced maternal and

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NICU hospitalizations. To accomplish this, the TennCare MCOs independently contract with Alere on a fee-for-service basis using a negotiated fee schedule that is separate and distinct from either the TennCare or Medicare fee schedules. Under this arrangement, the MCOs pay Alere out of their own pockets and do not seek reimbursement for Alere's services from TennCare. Simply stated, Alere is not paid with TennCare dollars. Nor do the MCOs submit encounter data regarding Alere's services to TennCare.

To be clear, however, Alere does participate directly in the TennCare program as a DME supplier. TennCare has issued a DME supplier provider number (#5440128) to Alere. It is our understanding that this fully satisfies any participation requirement that must be met in order for Alere to contract with the TennCare MCOs in the manner described above. To repeat, the MCOs do not pay Alere using the TennCare or Medicare fee schedules and do not seek reimbursement for Alere's services from TennCare.

Should the Agency have any further questions on this topic, Alere has arranged for HSDA staff to speak with Mr. Kit Dockery, Principal, Ancillary Networks, at BlueCare. Mr. Dockery is very familiar with this topic, and we are happy to facilitate a discussion as needed.

7. Section C, Need Item 5 and 6 (Historical and Projected Utilization)

c. Contractual adjustments from charges amounts to approximately 60% of gross operating revenue. It seems that the applicant's high TennCare mix (71% average) may be the primary factor that accounts for the large amounts provided for contractual adjustments in Year 1 and Year 2. Please clarify by describing how TennCare reimburses for the applicant's services.

The TennCare MCO's--not TennCare--contract with Alere at a pre-negotiated per diem rate. Each MCO pays 100% of its negotiated rate.

d. Net Operating Revenue in the Historical Data Chart and the Projected Data Chart (current and proposed counties chart version) differs from the amounts shown in Table 16 on page 56 (payor mix profile table). Please clarify.

Table Sixteen on page 56 was designed to show payor mix data before contractual adjustment for bad debt. The Historical and Projected Data Charts are full income and expense statements that specifically require showing and deducting bad debt. To use 2014 as an example, the Historical Data Chart for 2014 shows net operating revenue after deduction of \$22,985 of Bad Debt. If you add that bad debt amount back into net operating revenue, you have a total of \$673,189, as Alere's financial staff showed in Table 16.

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e. Using the staffing plan shown in Table 18 on page 60, the \$45,373 allocated in Year 1 for salaries and wages expense (Line D.1) for the additional 4.8 FTE per diem nursing staff for the 22 counties appears to be understated. Please clarify.

The Table Eighteen staffing plan on page 60 shows current year (2015) salary ranges. Alere has changed the way it pays its per diem nursing staff, resulting in paying less in patient educator fees and converting the per diem employees from a PRN model to part time or full time employees. So Years One and Two on the Projected Data Chart, which are 2016-2017, accurately reflect what will be paid.

f. Please clarify why the \$1,786,408 gross operating revenue in the Historical Data Chart (\$8,932/patient) differs from the \$1,706,408 (\$8,532/patient) in Table 14 on page 53.

The gross revenue amount in Table Fourteen contained a typographical error. The accurate figure is \$1,786,408, as in the Historical Data Chart. So Table Fourteen should be identical, with an average gross charge of \$8,932. Attached at the end of this letter is revised page 53R correcting the Table.

8. Section C, Economic Feasibility Item 2 and Item 4

b. Review of the Consolidated Balance Sheets for the parent company revealed an excess of current liabilities over current assets for the 2013, 2014 and 2015 fiscal year periods such that the company's current ratio may be below industry norm. Although it is understood that the capital costs of the proposal are primarily consulting fees and are minimal, is sufficient cash from cash reserves available to support the project in light of United Health Group's current obligations (such as accounts payable) as identified in current liabilities?

Yes; sufficient cash reserves are available for this minimal project cost, regardless of the ratio. This is affirmed in the commitment letter from the Chief Financial Officer of Optum Health Care Solutions dated June 17, 2015.

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9. Section C. Economic Feasibility Item 5 (Average Gross Charges)

The response with charts is noted.

What accounts for the decrease from the average gross charge of \$8,930 in the Historical Data Chart in 2014 to the average gross charge of approximately \$6,787 per patient in Year 1 that is shown in Table 13B? Please clarify.

The decrease is due to a change in the mix of therapies/services Alere provided to patients. In 2014, Alere provided services with a higher average selling price ("ASP"), which resulted in higher revenues that year. The therapy mix has changed now; Alere is serving patients with therapies that have a lower ASP.

10. Section C, Economic Feasibility, Item 9

The projected payor mix information in Table 16 on page 56 of the application is noted.

a. As noted in an earlier question, the amounts for Net Revenue for 2014, Year 1 and Year 2 differ from the Historical and Projected Data Charts. Please explain.

Please see the response to question 7d above. Table Sixteen on page 56 was designed to show payor mix data before contractual adjustment for bad debt. The Historical and Projected Data Charts are full income and expense statements that specifically require showing and deducting bad debt. To use 2014 as an example, the Historical Data Chart for 2014 shows net operating revenue after deduction of \$22,985 of Bad Debt. If you add that bad debt amount back into net operating revenue, you have a total of \$673,189, as Alere's financial staff showed in Table 16.

Page Five
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11. Proof of Publication

Although referenced in the application, publisher's affidavits or copies of the LOI in newspaper article with date and mast intact was omitted from the application.

a. Please provide this information to confirm publication of the LOI on June 10, 2015 in all 13 of the newspapers identified in the list that HSDA received on June 10, 2015 with the LOI.

An additional newspaper proof of publication has been received since the last supplemental response; it is attached at the end of this letter.

Support Letters

As indicated in the previous response, support letters are not yet available. Alere knows that they are important in the staff review and is working to obtain as many as possible for simultaneous submittal. It was thought best to go ahead and get the specific supplemental responses to you as early as possible.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn
Consultant

ONLINE ONLY ABSOLUTE AUCTION
BIDDING ENDS JUNE 23
PRIME COMMERCIAL PROPERTY
11.72± ACRES
IN 2 TRACTS
JUST SOUTH OF I-40 EXIT #320 - CROSSVILLE, TN
TAYS 931.526.2307 WWW.TAYSAUCTIONS.COM

ESTATE AUCTION
Thursday, July 2nd @ 9:00 AM
453 Acres in 5 tracts
• House • Barns • Cattle • Equipment •
250 Hiltson Lane, Huntland, TN
VanMassey.com
for photos & more information
931-433-8686
Van Massey Auctions & Realty • TN Lic 31215

Rodeo

Continued from Page 1A

event was the use of a "Kiddie Pool" for the younger anglers.

The event drew visitors from as far away as Texas, Indiana, and Ohio for a chance to "catch a rainbow". Twelve large

display trout were also released to be caught.

Cosponsored by the U.S. Fish and Wildlife Service, Tennessee Wildlife Resources Agency (TWRA), U.S. Army Corps of Engineers (Corps), Friends of Dale Hollow National Fish Hatchery, Friends of Dale Hollow Lake, and the citizens of Clay

County, Tennessee the rodeo presents a unique opportunity for families to spend quality time together and to connect children with nature.

The role of master of ceremonies was shared by Clay County Sheriff Brandon Boone and TWRA Assistant Chief of Fisheries Frank Fies. Facepainting by

Teresa Nevans was available, the Friends Groups distributed free hot dogs, and Corps Ranger Bobby Bartlett manned a water safety information table.

Local and area businesses and individuals donated prizes, tackle, bait, drinks, advertising, and their time to help make the rodeo a success.

Rating

Continued from Page 1A

Fewer than 10% of the nation's banks can claim this title.

Established in 1919, today Macon Bank & Trust Company (www.

maconbankandtrust.com) operates through seven conveniently located branch offices in Celina, Lafayette, Red Boiling Springs and Westmoreland, Tennessee.

Karen L. Dorway, president of BauerFinancial notes that, for the first time, we see Big Banks acknowledging the value in relationship

banking. That's something community banks, like Macon Bank & Trust Company, have always known. In fact, she continues, because of their inherent focus on relationships, community banks are uniquely positioned to serve their communities in a way no one else can. Those relationships pay off for both Macon Bank &

Trust Company and the customers it serves.

BauerFinancial has been reporting on and analyzing the performance of US banks and credit unions since 1983. No institution can pay for or opt out of a BauerFinancial rating. Consumers may see star-ratings of other banks for free by visiting www.bauerfinancial.com.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Alere Women's and Children's Health LLC (a home health agency with its principal office in Davidson County), owned and managed by Alere Women's and Children's Health, LLC (a limited liability company), intends to file an application for a Certificate of Need to provide home health agency services exclusively limited to the care of high-risk obstetrical patients and newborns with congenital and postpartum needs, in the following counties, to be added to its current service area, at a cost estimated at \$34,000: Cannon, Clay, Cumberland, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Moore, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren, and White.

The applicant is licensed as a Home Health Agency by the Board for Licensing Health Care Facilities. The applicant's principal office is located at 1926 Hayes Street, Suite 111, Nashville, TN 37203. The project does not contain major medical equipment or facilities or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2015. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

BANK OF CELINA
CITIZENS BANK • LIBERTY STATE BANK
SMITH COUNTY BANK • TRADERS BANK

**Turn Your Everyday
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Cash Back!**



Library News

Special guests coming June 25

by JUDITH CUTRIGHT
Director of Library Services

The Clay County Library would like to remind all parents that story time is every Tuesday and Thursday at 9:30. Mr. Bond and the Science Guys will be here on Thursday, June 25, at 10:00.

The library will be closed on Friday, July 4.

New books in this week are "Married 'til Monday" by Denise Hunter, "Those Jensen Boys" by William W. Johnstone, "Tall of Shadows" by Loran Paine, "Amdish Promises" by Leslie Gould, "Together With You" by Victoria Bylin, "The Breaking Point" by Jefferson Bass, "A Heart's

Betrayal" by Colleen Coble, "The Darkling Child" by Terry Brooks, "All the Single Ladies" by Dorothea Benton Frank, "Second Life" by S. J. Watson, "The Fixer" by Joseph Finder, "Blueprints" by Barbara Delinsky, and "Dead Ice" by Laurell K. Hamilton. Come in and check us out!

Nanny's Favorites

Bible verses and recipes are reprinted from the late Edwina Naper's long-running "Food for Thought" column.

Fruit desserts sure do hit the spot

Bible Verse

Let the word of Christ dwell in you richly in all wisdom, teaching and admonishing one another in psalms and hymns and spiritual songs, singing with grace in your hearts unto the Lord.
Colossians 3:16

Cherry Salad

two (3 oz.) pkgs. cherry jello
2 cups boiling water
one (20 oz.) can crushed pineapple
one (21 oz.) can cherry pie filling
one (8 oz.) pkg. cream cheese
1/2 cup sugar
1/2 cup sour cream

1 teaspoon vanilla extract
1/2 cup chopped nuts
In a large bowl, combine Jello and hot water. Add pineapple and cherry pie filling. Pour into a 8 x 10 inch glass dish. Chill until set.

Soften cream cheese and mix well with sugar. Blend in sour cream and vanilla. Spread over gelatin mixture. Sprinkle with nuts. Serves 6.

Pineapple Pie

2/3 cup sugar
1/3 cup flour
1/4 teaspoon salt
3 tablespoons lemon juice

1 cup water
1 cup crushed pineapple (small can)
3 egg yolks
2 tablespoons butter
one baked pie shell
Blend sugar, flour and salt. Add lemon juice, water, pineapple and egg yolks and mix well. Cook over low heat until thick; add butter and stir until well mixed. Pour into baked pie shell.

Make meringue of egg whites and 1/3 cup sugar. Place on pie and brown in 325 degree oven.

In memory of
**EDWINA
NAPER**

Obituaries

Gene Hickman, 77
RED BOILING SPRINGS—Funeral services for Gene Hickman of Hermitage Springs were conducted

followed in the Hermitage Springs Cemetery. Pallbearers were Curtis Hickman, Lucas Hickman, Jace Fraley, Adam Bryant, Indalecio

Browning on September 18, 2010, who survives. Gene was a farmer and a member of the Hermitage Springs Church of

AFFIDAVIT

SUPPLEMENTAL

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

Alere Women's + Children's Health

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John L Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 16th day of July, 2018,
witness my hand at office in the County of DAVIDSON, State of Tennessee.

[Signature]
NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02



SUPPLEMENTAL #2

July 29, 2015
9:27 am

July 28, 2015

Jeff Grimm, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1506-025
Alere Women's and Children's Health

Dear Mr. Grimm:

This letter responds to the questions remaining in your July 24 request for supplemental information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

5. Section C, Need, Item (Project Specific Criteria_

(a) Items 5.A and 5.C – It is understood that the applicant is gathering the requested letters from physicians and residents of the proposed 22 counties. However, the applicant should be aware that if the information is not submitted by month end, HSDA's initial review of the application will continue in accordance with the process described in the closing section of this letter below.

The response indicating that the applicant is continuing to gather letters of support is noted. Just to add to the original request, the applicant may wish to include letters of support for its proposed services from management representatives of hospitals located in the proposed additional 22 counties. As a reminder, initial review of the application must be completed by the August 19, 2015 date noted in the instructions contained in the last section of this letter below.

Regrettably, support letters are not yet available. Alere knows that they are important in the staff review and will continue to work diligently with physicians and organizations who serve these patients to put their support in writing.

July 29, 2015**9:27 am**

Page Two
July 28, 2015

7. Section C, Need Item 5 and 6 (Historical and Projected Utilization)

- (d) Net Operating Revenue in the Historical Data Chart and the Projected Data Chart (current and proposed counties chart version) differs from the amounts shown in Table 16 on page 56 (payor mix profile table). Please clarify.

The responses for items 7.c through 7.f are noted.

In your response for Item 7.d, you explained that the \$673,189 Net Operating Revenue amount shown in Table 16 is Net Operating Revenue before \$22,985 of bad debt expense. The response is understood. Thank you for the clarification.

However, HSDA would appreciate clarification of Table 11-B that identifies \$637,027 for total gross revenue reported to the Tennessee Department of Health (TDH) for the 2014 Joint Annual report (JAR) reporting period. Since TDH defines total gross revenue as total charges on page 3 of the provider JAR, it is unclear why the \$1,786,408 total gross operating revenue in the 2014 Historical Data Chart on page 49 of the application would not be the amount that the applicant reported to TDH in the 2014 provider JAR. Please explain.

Schedule D--Finances, in the Joint Annual Report, instructs the preparer to *"Enter the amount of gross revenue (your total charges) that your organization received from each of the sources listed during the reporting period.*

Alere understands this to be the contracted rates Alere has pre-negotiated with all payors. They are reported as net revenue because they are the amounts that are (a) *billed to*, and (b) *actually received from*, the payors. That is the only way for Alere to follow the JAR instructions as they are currently written.

July 29, 2015**9:27 am**

Page Three
July 28, 2015

1. Proof of Publication

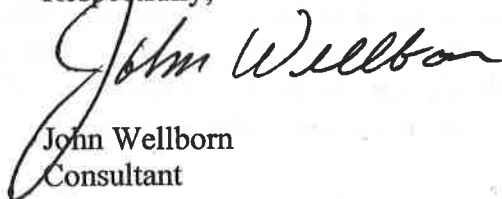
Although referenced in the application, publisher's affidavits or copies of the LOI in newspaper article with date and mast intact was omitted from the application. Please provide this information to confirm publication of the LOI on June 10, 2015 in all 13 of the newspapers identified in the list that HSDA received on June 10, 2015 with the LOI.

Thank you for submitting the proof of publication of the LOI on June 10, 2015 for the Dale Hollow Horizon. Please complete the table below to highlight general information about the paper.

County	Name of Newspaper of General Circulation	Address	Date LOI Published	How often is this Newspaper Distributed?
Clay	Dale Hollow Horizon	121 Donaldson Ave P.O. Box 69 Celina, TN 38551	June 10, 2015	Weekly

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn
Consultant

July 29, 2015

ONLINE ONLY AUCTION
BIDDING ENDS JUNE 23
PRIME COMMERCIAL PROPERTY
11.72± ACRES
IN 2 TRACTS
 JUST SOUTH OF I-40 EXIT #320 - CROSSVILLE, TN
 931.516.2167 WWW.TAYSAUCTIONS.COM
TAYS

ESTATE AUCTION
 Thursday, July 2nd @ 9:00 AM
 453 Acres in 5 tracts
 • House • Barns • Cattle • Equipment •
 250 Hittson Lane, Huntland, TN
VanMassey.com
 for photos & more information
931-433-8686
 Van Massey Auction & Realty - TN Lic #52233

Rodeo

Continued from PAGE 1A

event was the use of a "Kiddie Pool" for the younger anglers.

The event drew visitors from as far away as Texas, Indiana, and Ohio for a chance to "catch a rainbow". Twelve large

display trout were also released to be caught.

Cosponsored by the U.S. Fish and Wildlife Service, Tennessee Wildlife Resources Agency (TWRA), U.S. Army Corps of Engineers (Corps), Friends of Dale Hollow National Fish Hatchery, Friends of Dale Hollow Lake, and the citizens of Clay

County, Tennessee, the rodeo presents a unique opportunity for families to spend quality time together and to connect children with nature.

The role of master of ceremonies was shared by Clay County Sheriff Brandon Boone and TWRA Assistant Chief of Fisheries Frank Fiss. Facepainting by

Teresa Nevans was available, the Friends Groups distributed free hot dogs, and Corps Ranger Bobby Bartlett manned a water safety information table.

Local and area businesses and individuals donated prizes, tackle, bait, drinks, advertising, and their time to help make the rodeo a success.

Rating

Continued from PAGE 1A

Fewer than 10% of the nation's banks can claim this title.

Established in 1919, today Macon Bank & Trust Company (www.

maconbankandtrust.com) operates through seven conveniently located branch offices in Celina, Lafayette, Red Boiling Springs and Westmoreland, Tennessee.

Karen L. Dorway, president of BauerFinancial notes that, for the first time, we see Big Banks acknowledging the value in relationship

banking. That's something community banks, like Macon Bank & Trust Company, have always known. In fact, she continues, because of their inherent focus on relationships, community banks are uniquely positioned to serve their communities in a way no one else can. Those relationships pay off for both Macon Bank &

Trust Company and the customers it serves."

BauerFinancial has been reporting on and analyzing the performance of U.S. banks and credit unions since 1983. No institution can pay for or opt out of a BauerFinancial rating. Consumers may see star-ratings of other banks for free by visiting www.bauerfinancial.com.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Alere Women's and Children's Health LLC (a home health agency with its principal office in Davidson County), owned and managed by Alere Women's and Children's Health, LLC (a limited liability company), intends to file an application for a Certificate of Need to provide home health agency services exclusively limited to the care of high-risk obstetrical patients and newborns with antepartum and postpartum needs, in the following counties, to be added to its current service area, at a cost estimated at \$84,000: Cannon, Clay, Cumberland, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Moore, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren, and White.

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Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
 Andrew Jackson Building, 9th Floor
 502 Deaderick Street
 Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(e)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

BANK OF CELINA
 CITIZENS BANK • LIBERTY STATE BANK
 SMITH COUNTY BANK • TRADERS BANK

**Turn Your Everyday
 Purchases Into
 Cash Back!**



Library News

Special guests coming June 25

By JUDITH CUTRIGHT
 Director of Library Services

The Clay County library would like to remind all parents that Story Time is every Tuesday and Thursday at 9:30. Mr. Bond and the Science Guys will be here on Thursday, June 25, at 10:00.

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Betrayal" by Colleen Coble, "The Darling Child" by Terry Brooks, "All the Single Ladies" by Dorothea Benton Frank, "Second Life" by S. J. Watson, "The Fixer" by Joseph Finder, "Blueprints" by Barbara Delinsky, and "Dead Ice" by Laurell K. Hamilton. Come in and check us out!

Nanny's Favorites

Bible verses and recipes are reprinted from the late Edwina Napier's long-running "Food for Thought" column.

Fruit desserts sure do hit the spot

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Pineapple Pie

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 1/4 teaspoon salt
 3 tablespoons lemon juice

1 cup water
 1 cup crushed pineapple (small can)
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 2 tablespoons butter
 one baked pie shell
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Make meringue of egg whites and 1/3 cup sugar. Place on pie and brown in 325 degree oven.

In memory of
**EDWINA
 NAPIER**

Obituaries

Gene Hickman, 77
 RED BOILING SPRINGS—Funeral services for Gene Hickman of Hermitage Springs were conducted

followed in the Hermitage Springs Cemetery. Pallbearers were Curtis Hickman, Lucas Hickman, Jace Fraley, Adam Bryant, Indalecio

Browning on September 18, 2010, who survives. Gene was a farmer and a member of the Hermitage Springs Church of

July 29, 2015

9:27 am

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

Alum Women's & Children's Health - Davidson

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 29th day of July, 2015,
witness my hand at office in the County of DAVIDSON, State of Tennessee.

J. M. Danforth
NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02



Supplemental #2a -COPY-

Alere Women's and
Children's Health

CN1506-025

July 30, 2015

1:33 pm

DSG Development Support Group

July 29, 2015

Jeff Grimm, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1506-025
Alere Women's and Children's Health

Dear Mr. Grimm:

This letter responds to your last remaining request for additional information on this application. The item below is numbered to correspond to your original question. It is provided in triplicate, with affidavit.


5. Section C, Need, Item (Project Specific Criteria_

a. Items 5.A and 5.C – It is understood that the applicant is gathering the requested letters from physicians and residents of the proposed 22 counties. However, the applicant should be aware that if the information is not submitted by month end, HSDA's initial review of the application will continue in accordance with the process described in the closing section of this letter below.

Please see the attached support letters from Dr. Bruce Beyer, Medical Director of Vanderbilt University Medical Center's Center for Women's Health, and from Dr. Etoi Garrison, of the Maternal Fetal Medicine Department of Vanderbilt University Medical Center. There was not room for both signatures on this letter so the physicians signed identical letters. Please note that they say their support is "on behalf of dozens of women's health physicians and other professionals at the Vanderbilt Center for Women's Health."

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,


John Wellborn
Consultant



July 30, 2015

1:33 pm

July 29, 2015

Melanie M. Hill
Executive Director
Tennessee Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Alere Women's and Children's Health, LLC
CON Application No. 1506-025

Dear Ms. Hill:

On behalf of dozens of women's health physicians and other professionals at the Vanderbilt Center for Women's Health, I want to make you aware of our strong support for the certificate of need application submitted by Alere Women's and Children's Health LLC. Alere specializes in caring for the unique medical needs of high-risk pregnant women and their newborns in the home. We have a long track record of success in partnering with Alere to care for our special needs patients, and we are eager to make those services available to patients throughout Middle Tennessee. This much-needed project will greatly assist with the orderly development of healthcare throughout the Middle Tennessee region and beyond.

We have one of the largest women's health practices in Tennessee. Our board-certified physicians, nurse midwives, nurse practitioners and research teams provide care in five specialty areas, including general obstetrics and maternal fetal medicine. Many of our patients are at risk of delivering prematurely or have other pregnancy-related complications – such as pregnancy-related hypertension or diabetes. These conditions pose a serious threat to the health of the mother and child and require close monitoring and regular care. For example, patients with a history of preterm labor often need weekly injections of highly specialized medications that are designed to reduce premature delivery. This progesterone (17P) therapy is a critical tool in combating Tennessee's Pre-term Birth rates, and utilizing Alere's OB Homecare service allows us to be sure that our patients are receiving optimal benefit.

Currently, Alere services are only available in 14 Middle Tennessee counties, which impact our ability to provide consistent care and options for our outreach patients, and eliminate clinical care decisions based on geographic location. The therapeutic benefit of this treatment is critical to the injection being given every 7 days. The main reason for noncompliance with this prescribed therapy is due to the challenges that surround patients needing to come into the office on a weekly basis. Using the latest technology and a team of registered OB nurses, Alere has the ability to access the patient's home, ensuring strict compliance. This provides better outcomes for our patients and reduces the high cost of avoidable NICU and hospital admissions.

We rely on Alere, and appreciate the opportunity to express our support for this application. We hope the Agency will take favorable action and grant the requested certificate of need.

Sincerely,

Bruce Beyer, MD
Medical Director
Center for Women's Health

July 30, 2015
1:33 pm

July 29, 2015

Melanie M. Hill
Executive Director
Tennessee Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Alere Women's and Children's Health, LLC
CON Application No. 1506-025

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We rely on Alere, and appreciate the opportunity to express our support for this application. We hope the Agency will take favorable action and grant the requested certificate of need.

Sincerely,

Etoi Garrison, MD
Maternal Fetal Medicine
Vanderbilt

July 30, 2015

1:33 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

Allure Women's & Children's Health

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 30th day of July, 2015,
witness my hand at office in the County of DAVIDSON, State of Tennessee.

[Signature]
NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02



July 31, 2015

Jeff Grimm, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1506-025
Alere Women's and Children's Health

Dear Mr. Grimm:

This letter responds to your last remaining request for additional information on this application. The item below is numbered to correspond to your original question. It is provided in triplicate, with affidavit.

5. Section C, Need, Item (Project Specific Criteria_

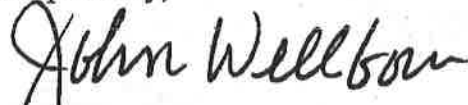
a. Items 5.A and 5.C – It is understood that the applicant is gathering the requested letters from physicians and residents of the proposed 22 counties.....

Attached are newly received support letters for the project, following up on the two from Vanderbilt Medical Center that we submitted on July 30. These new letters are from:

- Amerigroup, one of the State's major MCO's;
- Tennessee Maternal Fetal Medicine, PLC, a Saint Thomas Health-affiliated physician group officed in Davidson, Williamson, and Rutherford Counties;
- Two patients/consumers who have difficulty getting access to the types of services Alere provides, because Alere is not authorized to serve their counties.

If more is needed please email or telephone me so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn
Consultant

July 30, 2015

Melanie M. Hill
Executive Director
Tennessee Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Alere Women's and Children's Health, LLC
CON Application No. 1506-025

Dear Ms. Hill:

I want to express Amerigroup Tennessee, Inc.'s strong support for the certificate of need application filed by Alere Women's and Children's Health, LLC.

Since 2007, Amerigroup has been one of two health plans that provide health care coverage to persons who qualify for TennCare in the Middle Tennessee region. We work with Alere on a regular basis to care for our TennCare members, and we rely on Alere's specialized expertise to assist us in providing high-quality, personalized care at an affordable cost.

With its single focus on caring for high-risk pregnancy women and their children, Alere is an ideal partner to assist us in this important work. Alere's obstetrical nurses are uniquely qualified to treat patients who need 17P and to do the regular and careful monitoring that those patients need. Alere's nurses are on call and available 24 hours a day. This high level of supervision and monitoring of high-risk patients significantly reduces the cost of care and improves maternal and fetal health. No other home health agency can provide the specialized services to the high-risk pregnancy population offered by Alere.

Amerigroup is, therefore, very eager to see that Alere's services are available throughout all Middle Tennessee counties. Approval of Alere's certificate of need application will improve access to this important, very specialized kind of care and result in important cost savings for the State of Tennessee, and we encourage your Agency to approve the application at the earliest opportunity.

Thank you for your attention in this matter. Please do not hesitate to contact me with any questions.

Sincerely,



JoAnne Hunnicutt, LPN
Amerigroup
Maternal/Child Program Manager
615-232-2129



July 30, 2015

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

**Re: Alere Women's and Children's Health, LLC
CON Application No. 1506-025**

Dear Ms. Hill:

The physicians and staff at Tennessee Maternal Fetal Medicine PLC want to express our support for Alere Women's and Children's Health LLC's certificate of need application to expand its services in Middle Tennessee. There is a significant need for expanded access to the valuable services that Alere provides, and we are confident that the approval of this project will both assist in reducing costs and improve the orderly development of healthcare in our region. We urge you to give Alere's application your approval.

Tennessee Maternal Fetal Medicine is a specialty medical practice that focuses on prenatal diagnosis and treatment for obstetrical complications and other fetal concerns. Indeed, many of our patients struggle with "high risk" pregnancy-related conditions that threaten the health of the mother, the child or both. We work with Alere on a regular basis in caring for these patients. Unlike other home health agencies, Alere focuses its services exclusively on high risk obstetrical patients. The excellent home health services provided by Alere reduce the costs of pre- and post-natal care. Unfortunately, at present, we are not able to use Alere's services throughout Middle Tennessee due to the geographic limitation of its service area.

For all of these reasons, we enthusiastically endorse Alere's application for a certificate of need. Alere's services are needed by patients located through all 36 counties in the Middle Tennessee region, and the expansion of Alere's service territory will improve the quality of care that we are able to provide. Again, we urge you to approve Alere's application. Please do not hesitate to contact me with any questions.

Sincerely,



Cornelia R. Graves, MD
Medical Director
Tennessee Maternal Fetal Medicine

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Alere Women's and Children's Health CON Application No. 1506-025

Dear Ms. Hill,

My name is Tabitha Osborne and I am writing to offer my support of Alere's application to expand their coverage throughout middle Tennessee.

I am a resident of Lewis County, and Alere services were recommended and prescribed for me by my physician. I have a history of delivering prematurely, and my physician prescribed weekly 17P injections in an effort to reduce the likelihood that I will have another preterm birth. It goes without saying that delivering a premature baby is not only very costly, but is also very, very stressful.

Imagine my excitement to learn that there is a treatment to decrease the incidence of preterm birth. That excitement led to disappointment and frustration when I learned that I could not receive what is standard of care, and the best care possible for me and my unborn baby, simply because I live in Lewis County.

Please note that there are no home care agencies in my county that can provide the care that my physician has ordered, and I am not receiving the recommended care.

Ms. Hill, I am sure you would agree that services designed to promote better pregnancy outcomes should be readily available to all women in the state of Tennessee – not only the women who live where Alere has existing CON licensure. I strongly encourage you to remove all barriers that prevent women access to the much-needed home care services that Alere provides.

Sincerely,



Tabitha Osborne

641 Edgefield Dr.

Hohenwald, TN, 38462

931-628-1085

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Alere Women's and Children's Health CON Application No. 1506-025

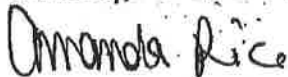
Dear Ms. Hill,

My name is Amanda Rice and I am writing to offer my support of Alere's application to expand their coverage throughout middle Tennessee.

During my pregnancy, my doctor referred me to Alere for 17P injections, as I had delivered prematurely with a prior pregnancy. After discussing this plan of care with my doctor, I was referred to Alere to provide the weekly injections that are proven to reduce the incidence of recurrent preterm birth. I was very disappointed to learn that while Alere does provide their care and services in some counties of TN, I live in a county in which they do not currently hold a Certificate of Need.

It is my opinion that the services that Alere offers to patients experiencing high risk pregnancies should be available to all women in the state of Tennessee. I offer my strong support of Alere's efforts to expand their reach, as it would help countless women throughout the state.

Sincerely,



Amanda Rice
10230 Hwy 641 N Unit A
Puryear, Tn 38251

SUPPLEMENTAL

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

Altre Women and Children's Health

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 31st day of July, 2018,
witness my hand at office in the County of DAVIDSON, State of Tennessee.

Jan M. Danforth
NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02



JUL 31 15 PM 3:49

(n) the *Herald-Citizen*, which is a newspaper of general circulation in Putnam County;

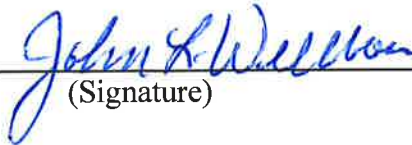
(o) the *Daily News Journal*, which is a newspaper of general circulation in Rutherford County; and

(p) the *Hartsville Vidette*, which is a newspaper of general circulation in Trousdale County.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that Alere Women's and Children's Health LLC (a home health agency with its principal office in Davidson County), owned and managed by Alere Women's and Children's Health, LLC (a limited liability company), intends to file an application for a Certificate of Need to provide home health agency services exclusively limited to the care of high-risk obstetrical patients and newborns with antepartum and postpartum needs, in the following counties, to be added to its current service area, at a cost estimated at \$84,000: Cannon, Clay, Cumberland, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Moore, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren, and White.

The applicant is licensed as a Home Health Agency by the Board for Licensing Health Care facilities. The applicant's principal office is located at 1926 Hayes Street, Suite 111, Nashville, TN 37203. The project does not contain major medical equipment or initiate or discontinue any other health service; and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2015. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

 6-9-15

(Signature)

(Date)

jwdsg@comcast.net
(E-mail Address)

2010-15-2:39

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published on or before June 10, 2015, for one day, in the following newspapers:

(a) the *Tennessean*, which is a newspaper of general circulation in Cannon, Clay, DeKalb, Fentress, Franklin, Giles, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Overton, Pickett, Putnam, Smith, Stewart, Trousdale, Van Buren and White Counties;

(b) the *Southern Standard*, which is a newspaper of general circulation in Cannon, DeKalb, Van Buren, Warren and White Counties;

(c) the *Cannon Courier*, which is a newspaper of general circulation in Cannon County;

(d) the *Dale Hollow Horizon*, which is a newspaper of general circulation in Clay County;

(e) the *Crossville Chronicle*, which is a newspaper of general circulation in Cumberland County;

(f) the *Smithville Review*, which is a newspaper of general circulation in DeKalb County;

(g) the *Dickson Herald*, which is a newspaper of general circulation in Dickson County;

(h) the *Fentress Courier*, which is a newspaper of general circulation in Fentress County;

(i) the *Lawrence County Advocate*, which is a newspaper of general circulation in Lawrence County;

(j) the *Elk Valley Times*, which is a newspaper of general circulation in Lincoln County;

(k) the *Daily Herald*, which is a newspaper of general circulation in Maury County;

(l) the *Leaf-Chronicle*, which is a newspaper of general circulation in Montgomery, Stewart and Houston Counties;

(m) the *Moore County News*, which is a newspaper of general circulation in Moore County;

— — — — —





July 30, 2015

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

**Re: Alere Women's and Children's Health, LLC
CON Application No. 1506-025**

Dear Ms. Hill:

The physicians and staff at Tennessee Maternal Fetal Medicine PLC want to express our support for Alere Women's and Children's Health LLC's certificate of need application to expand its services in Middle Tennessee. There is a significant need for expanded access to the valuable services that Alere provides, and we are confident that the approval of this project will both assist in reducing costs and improve the orderly development of healthcare in our region. We urge you to give Alere's application your approval.

Tennessee Maternal Fetal Medicine is a specialty medical practice that focuses on prenatal diagnosis and treatment for obstetrical complications and other fetal concerns. Indeed, many of our patients struggle with "high risk" pregnancy-related conditions that threaten the health of the mother, the child or both. We work with Alere on a regular basis in caring for these patients. Unlike other home health agencies, Alere focuses its services exclusively on high risk obstetrical patients. The excellent home health services provided by Alere reduce the costs of pre- and post-natal care. Unfortunately, at present, we are not able to use Alere's services throughout Middle Tennessee due to the geographic limitation of its service area.

300 20th Avenue N., Suite 702
Nashville, TN 37203

1800 Medical Center Pkwy, Suite 320
Murfreesboro, TN 37129

100 Covey Drive, Suite 207
Franklin, TN 37067

(615) 284-8636 (TMFM) | Fax (615) 284-8637 | www.tnmfm.com

For all of these reasons, we enthusiastically endorse Alere's application for a certificate of need. Alere's services are needed by patients located through all 36 counties in the Middle Tennessee region, and the expansion of Alere's service territory will improve the quality of care that we are able to provide. Again, we urge you to approve Alere's application. Please do not hesitate to contact me with any questions.

Sincerely,



Cornelia R. Graves, MD
Medical Director
Tennessee Maternal Fetal Medicine



Middle Tennessee Women's Health Group

Obstetrics & Gynecology

726-844-5171 x336

Karen F. Davis, MD • Terry L. Whitten, MD • Lisa A. Phillips, MD • Carrie C. Marchman, MD
Julie M. Taggart, DO • Michele Gibson-O'Grady, NP, CNM • LeAnn Gordon, CFNP, RNFA
Terry Zimmer, CNM • Megan Manor, WHANP

August 19, 2015

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Alere Women's and Children's Health, LLC
CON Application No. 1506-025

Dear Ms. Hill:

On behalf of Middle Tennessee Women's Health Group, please allow me to add our enthusiastic support for the above-referenced certificate of need application. This project is most deserving of approval, and we sincerely hope that you, your capable staff and the members of the Agency will give it favorable consideration. We have worked with Alere for many years, and the approval of this much-needed project will greatly assist our practice caring for pregnant women in the southern Middle Tennessee region.

Our practice works with patients in three offices—Spring Hill (Williamson County), Columbia (Maury County), and Lawrenceburg (Lawrence County). Given our locations, many of our patients live in rural counties and cannot immediately access obstetrical services when high-risk situations develop. The specialized home health services provided by Alere mitigate this situation and give many rural high-risk patients access to a level and quality of care that is difficult to find outside of larger cities. This is particularly true with our patients with prior Pre-Term Birth (PTB) needing weekly progesterone (17-P) therapy to help delay or prevent subsequent preterm deliveries. This treatment has been fully supported by ACOG and nearly every other obstetrical thought-leader, but remains a difficult program to administer and maintain the necessary compliance, given that it's intended to be a RN administered, weekly IM shot - for potentially 20 weeks! By using Alere's OB RN Homecare nurses to administer the shots, do weekly assessments, while monitoring compliance and other signs and symptoms, they are proven to significantly reduce the cost of care and improve upon maternal and fetal health.

At present, however, the valuable services offered by Alere are available in only 14 Middle Tennessee counties. This impacts our practice directly - we can refer our patients to Alere in Spring Hill and Columbia, but not patients in the other counties surrounding our practice offices. We feel it is in the best interest of all patients to make Alere's services available in the 36 counties surrounding Middle Tennessee. We strongly believe that each and every patient of ours should be offered the same level of care and services. The approval of this application will afford all patients the same access to health services and will not discriminate based on geographic location.

Again, our practice is proud to lend its support to the Alere application. Please do not hesitate to let me know if there is anything more we can do to support this important initiative.

Sincerely,

Dr. Lisa A. Phillips, MD

Columbia
808 Jenland Dr.

Lawrenceburg
726 N. Locust Ave.

Spring Hill
1003 Reserve Blvd.

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Alere Women's and Children's Health CON Application No. 1506-025

Dear Ms. Hill,

My name is Tabitha Osborne and I am writing to offer my support of Alere's application to expand their coverage throughout middle Tennessee.

I am a resident of Lewis County, and Alere services were recommended and prescribed for me by my physician. I have a history of delivering prematurely, and my physician prescribed weekly 17P injections in an effort to reduce the likelihood that I will have another preterm birth. It goes without saying that delivering a premature baby is not only very costly, but is also very, very stressful.

Imagine my excitement to learn that there is a treatment to decrease the incidence of preterm birth. That excitement led to disappointment and frustration when I learned that I could not receive what is standard of care, and the best care possible for me and my unborn baby, simply because I live in Lewis County.

Please note that there are no home care agencies in my county that can provide the care that my physician has ordered, and I am not receiving the recommended care.

Ms. Hill, I am sure you would agree that services designed to promote better pregnancy outcomes should be readily available to all women in the state of Tennessee – not only the women who live where Alere has existing CON licensure. I strongly encourage you to remove all barriers that prevent women access to the much-needed home care services that Alere provides.

Sincerely,

A handwritten signature in cursive script that reads "Tabitha Osborne".

Tabitha Osborne

641 Edgefield Dr.

Hohenwald, TN, 38462

931-628-1085

**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954**

DATE: August 31,2015

APPLICANT: Alere Woman's and Children's Health
1926 Hayes Street, Suite 111
Nashville, Tennessee 37203

CN1506-025

CONTACT PERSON: John Wellborn, Consultant
Development Support Group
4219 Hillsboro Road, Suite 210
Nashville, Tennessee 37215

COST: \$84,000

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Alere Women's and Children's Health, LLC, (AWCH) seeks a Certificate of Need (CON) to provide home health services exclusively to the care of high-risk obstetrical patients and newborns with antepartum and postpartum needs by adding 22 counties to its current service area.

AWCH is a licensed home health agency. The applicant's principal office is located at 1926 Hayes Street, Suite 111, Nashville, Tennessee 37203. The project does not contain any major medical equipment or initiate or discontinue any other health service; nor affect any facilities licensed bed compliments.

AWCH, LLC is wholly owned by Alere Health, LLC, which is wholly owned by Optum Health Care Solution's, Inc. and is ultimately owned by United Health Group. Attachment A.4. contains more detailed information and an organizational chart for Optum and its subsidiaries.

The total project cost is \$84,000 and will be funded through cash reserves as documented by letter in Attachment C, Economic Feasibility.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The applicant's service area contains the following counties.

County	2015 Population	2019 Population	% of Increase/ (Decrease)
Cannon	14,218	14,631	2.9%
Clay	7,681	7,684	0.0%
Cumberland	58,340	61,077	4.7%
DeKalb	18,996	19,172	0.9%
Fentress	18,553	19,133	3.1%
Franklin	43,391	42,408	2.5%

Giles	29,293	29,282	0.0%
Humphreys	18,518	18,581	0.3%
Jackson	11,383	11,520	1.2%
Lawrence	42,373	42,373	0.0%
Lewis	12,112	12,259	1.2%
Lincoln	34,624	36,059	4.1%
Macon	23,419	24,366	4.0%
Moore	28,652	29,125	1.7%
Overton	22,593	23,104	2.3%
Pickett	4,998	4,930	-1.4%
Putnam	78,416	83,992	7.1%
Smith	19,771	20,468	3.5%
Stewart	13,659	14,027	2.7%
Trousdale	8,275	8,667	4.7%
Van Buren	5,433	5,488	1.0%
White	27,132	28,275	4.2%
Total	541,830	556,621	2.7%

Tennessee Population Projections 2000-2020, 2015 Revised UTCBER, Tennessee Department of Health

Females of Child Bearing Age Population-15 to 44

County	2015 Population	2017 Population	% of Increase/ (Decrease)
Cannon	2,370	2,349	-0.9%
Clay	1,155	1,134	-1.8%
Cumberland	8,518	8,564	0.5%
DeKalb	3,287	3,293	0.2%
Fentress	3,030	2,980	-1.7%
Franklin	7,570	7,537	-0.4%
Giles	5,097	4,960	-2.7%
Humphreys	3,179	3,155	-0.8%
Jackson	1,906	1,838	-0.8%
Lawrence	7,390	7,488	1.3%
Lewis	2,159	2,128	-1.4%
Lincoln	5,755	5,705	-0.9%
Macon	4,252	4,312	1.4%
Moore	1,123	1,141	1.6%
Overton	3,918	3,939	0.5%
Pickett	692	641	-7.4%
Putnam	15,837	16,452	3.9%
Smith	3,612	3,634	0.6%
Stewart	2,311	2,289	-1.0%
Trousdale	1,513	1,553	2.6%
Van Buren	850	826	-2.8%
White	4,596	4,685	1.9%
Total	90,120	90,620	0.6%

Tennessee Population Projections 2000-2020, 2015 Revised UTCBER, Tennessee Department of Health

AWCH is a highly specialized home health agency that has served fourteen Middle Tennessee counties for many years. It is one of three Alere home health agencies in Tennessee, and is part of a national network of Alere agencies supported by regional clinical centers that electronically monitor health status of Alere patients and participate in the patients care.

AWCH works with, and under the direction of patients' physicians, to provide clinically state-of-the-art home care exclusively to high-risk obstetrical patients and newborns for their antepartum and postpartum care. Alere does not provide any other type of home health services.

Alere is proposing to add twenty-two counties to the service area of its Davidson County principal office to be able to serve referring physicians' patients where ever they live in the Middle Tennessee area. Alere's application is the first of three applications being submitted to expand Alere's three service areas from 34 relatively populous counties to all 95 counties, including the least populous and lowest income counties.

Alere identifies the need for their services based on the following points:

- Alere's programs protect the lives of physician/payor identified high risk expectant mothers, and prevent fetal and newborn health problems that impose high medical and societal costs during and after pregnancy. Alere's interventions reduce costly emergency room visits, maternal hospitalizations, and newborn admissions to Neonatal Intensive Care Units (NICU). Alere states they have positive impacts on restraining costs of care and on increasing high quality outcomes that have resulted in strong physician and insurer support where ever it operates. According to the applicant, approximately 72% of the agency's patients are TennCare mothers, which provide fiscal benefits to State government.

2014 Alere Women's and Children's Health Tennessee

County	Patients	Patient Days	TennCare Percentage	TennCare Revenue	Commercial Percentage	Commercial Revenue
Davidson	186	13,842	47.98%	\$305,662	51.91%	330,665
Hamilton	41	42,959	54.00%	\$201,018	36.76%	\$136,851
Shelby	376	23,253	35.10%	\$440,733	63.07%	\$792,107
Totals						

Source: *Joint Annual Report of Home Health Agencies, 2014 (Final)*.

- The applicant states TennCare MCOs need universal availability of Alere's services throughout the State. Physicians, insurers, and patients need access to this unique level of care. Many home health agencies avoid serving the high risk population due to the risks of litigation and liability should things not go well.
- Approval of this project will result in greater accessibility to care for all high-risk pregnant women, especially TennCare patient who the applicant states are not adequately served today. Many of the patients Alere serves could potentially seek care at local emergency rooms or as hospital inpatients.
- Alere believes the expansion of its service area will have a minimal impact on other providers due to the unique and specialized nature of their services. In 2014, the applicant reports the 72 home agencies licensed in the 22 counties served 18,364 patients. Of the home health agencies identified who serve 18-64 females, the applicant polled 18 agencies as to whether they provided the service they are proposing. None of the 18 agencies polled responded that they provide these services. No agencies in the proposed service are dedicated to serving the population the applicant serves. Alere proposes to serve just 43 patients in year two of this project.

Some of the benefits of the interventions Alere provides are elimination of barriers to care such as transportation problems, childcare issues, missing scheduled visits, reduced costs of emergency room visits, maternal hospitalizations, NICU care, and future health and societal costs, and a cost savings of \$8,090 per birth in Medicaid savings.

TENNCARE/MEDICARE ACCESS:

The applicant will participate in the TennCare program. Alere contracts with AmeriGroup, United Healthcare Community Plan, and TennCare Select.

The applicant projects year one TennCare revenues of \$1,604,088.82, or 71.4% of total gross revenues. In year two, the applicant projects \$1,807,382.47 or 71.4% of total revenues.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment have reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and if the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located page 46 of the application. The total project cost is \$84,000.

Historical Data Chart: The Historical Data Chart is located on page 49 of the application. The applicant served 196, 202, and 186 patients in 2012, 2013, and 2014 with net operating revenues of \$417,968, \$133,898, and \$219,378 each year, respectively.

Projected Data Chart: The Projected Data Chart is located on page 50 of the application. Alere proposed to service 42 And 43 patients in the 22 new counties in 2016 and 2017 with net operating revenues of \$38,518 and \$38,245 each year respectively. Over all its counties, Alere projects 331 and 373 patients in 2016 and 2017, with net operating revenues of \$271,777 and \$301,032 each year, respectively.

Average gross charges for the proposed 22 counties are as follows:

	CY2016	CY2017
Patients	42	43
Average Gross Charge per Patient	\$6,779	\$6,779
Average Deduction per Patient	\$4,435	\$4,435
Average Net Charge per Patient	\$2,344	\$2,344
Average Net Operating Revenue Per Patient	\$939	\$911

Gross charges for all counties are as follows:

	CY2016	CY2017
Patients	331	373
Average Gross Charge per Patient	\$6,787	\$6,786
Average Deduction per Patient	\$4,440	\$4,440
Average Net Charge per Patient	\$2,347	\$2,347
Average Net Operating Revenue Per Patient	\$821	\$807

The applicant decided to pursue this project due to continuous requests from referring physicians to extend their services to a wider geographic service area. The choosing of the 22 counties was dictated by an internal long range plan to expand Alere in order to serve the TennCare population.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

Alere does not believe their projected 43 patients in year to will have a negative impact on service area providers, many of whom do not serve pregnant women.

The project will have a positive impact on the health of individuals in these rural counties. Tennessee is above the national average for premature births. The strongest impact of this project will be a reduction of costly emergency room visits, maternal acute care admissions, NICU admissions of preterm babies, and excessive visits to obstetricians' offices.

The applicant's current and projected staffing is located on page 60 of the application. The applicant will increase from 10 registered OB nurses to 24 by 2017. The days of service for these 14 additional registered nurses and call center staff will cumulatively total approximately 4.8 FTE equivalents. Of that, 4.0 FTE equivalents are cumulative per diems from the pool of qualified OB

registered nurses who are employed by Alere to perform home care services under Alere protocols and under the direction of physicians.

Alere is licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities and accredited by the Joint Commission. Alere earned a Gold Seal from the Joint Commission for system-wide excellence.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.
2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

The Department of Health, Division of Policy, Planning, and Assessment calculated the service area bed need surplus of (11,321) beds. No county in the designated service area has a need for new home health services. However, the applicant states the formula uses the entire population and not women of childbearing age that have high risk pregnancies that Alere projects.

3. Using recognized population sources, projections for four years into the future will be used.

The applicant's service area contains the following counties.

County	2015 Population	2019 Population	% of Increase/ (Decrease)
<i>Cannon</i>	<i>14,218</i>	<i>14,631</i>	<i>2.9%</i>
<i>Clay</i>	<i>7,681</i>	<i>7,684</i>	<i>0.0%</i>
<i>Cumberland</i>	<i>58,340</i>	<i>61,077</i>	<i>4.7%</i>
<i>DeKalb</i>	<i>18,996</i>	<i>19,172</i>	<i>0.9%</i>
<i>Fentress</i>	<i>18,553</i>	<i>19,133</i>	<i>3.1%</i>
<i>Franklin</i>	<i>43,391</i>	<i>42,408</i>	<i>2.5%</i>
<i>Giles</i>	<i>29,293</i>	<i>29,282</i>	<i>0.0%</i>
<i>Humphreys</i>	<i>18,518</i>	<i>18,581</i>	<i>0.3%</i>
<i>Jackson</i>	<i>11,383</i>	<i>11,520</i>	<i>1.2%</i>
<i>Lawrence</i>	<i>42,373</i>	<i>42,373</i>	<i>0.0%</i>
<i>Lewis</i>	<i>12,112</i>	<i>12,259</i>	<i>1.2%</i>
<i>Lincoln</i>	<i>34,624</i>	<i>36,059</i>	<i>4.1%</i>
<i>Macon</i>	<i>23,419</i>	<i>24,366</i>	<i>4.0%</i>
<i>Moore</i>	<i>28,652</i>	<i>29,125</i>	<i>1.7%</i>
<i>Overton</i>	<i>22,593</i>	<i>23,104</i>	<i>2.3%</i>
<i>Pickett</i>	<i>4,998</i>	<i>4,930</i>	<i>-1.4%</i>
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<i>Smith</i>	<i>19,771</i>	<i>20,468</i>	<i>3.5%</i>
<i>Stewart</i>	<i>13,659</i>	<i>14,027</i>	<i>2.7%</i>
<i>Trousdale</i>	<i>8,275</i>	<i>8,667</i>	<i>4.7%</i>
<i>Van Buren</i>	<i>5,433</i>	<i>5,488</i>	<i>1.0%</i>
<i>White</i>	<i>27,132</i>	<i>28,275</i>	<i>4.2%</i>
Total	541,830	556,621	2.7%

Tennessee Population Projections 2000-2020, 2015 Revised UTCBER, Tennessee Department of Health

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, an estimation will be made as to how many patients could be served in the future.

The Department of Health, Division of Policy, Planning, and Assessment calculated the service area bed need surplus of (11,321) beds.

5. Documentation from referral sources:

- a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

Alere provides letters from two Vanderbilt physicians in Supplemental 2a.

- b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The applicant projects 30 cases of Preterm Education, Nursing Surveillance, and 17P Administration; 5 cases of Nausea and Vomiting in Pregnancy;; 4 cases of Diabetes in Pregnancy; 2 cases of Hypertension in Pregnancy; and 1 case of Coagulation Disorders in Pregnancy.

- c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

Alere provides letters from two Vanderbilt physicians in Supplemental 2a.

- d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

Alere is a national leader in the provision of comprehensive and specialized care to high-risk pregnant women and their fetuses/newborns. There is no other provider in the service area that is focus on this population. The applicant is high accessible to TennCare patients.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.

- a. The average cost per visit by service category shall be listed.

The applicant states a comparison cannot be made bases on differences between their bundled charges of \$6,779. However, the applicant compared 5 area home health agencies' charges in Supplemental 1. Cost per visit of the other agencies varied from \$108 to \$136 a visit and a charge per patient of \$3,313 to \$9,515.

- b. The average cost per patient based upon the projected number of visits per patient shall be listed.

Average gross charges for the proposed 22 counties are as follows:

	CY2016	CY2017
Patients	42	43
Average Gross Charge per Patient	\$6,779	\$6,779

Average Deduction per Patient	\$4,435	\$4,435
Average Net Charge per Patient	\$2,344	\$2,344
Average Net Operating Revenue Per Patient	\$939	\$911

Gross charges for all counties are as follows:

	CY2016	CY2017
Patients	331	373
Average Gross Charge per Patient	\$6,787	\$6,786
Average Deduction per Patient	\$4,440	\$4,440
Average Net Charge per Patient	\$2,347	\$2,347
Average Net Operating Revenue Per Patient	\$821	\$807